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ABSTRACT

This participant manual is designed to provide an overview of federal laws and regulations pertaining to the confidentiality of alcohol and drug abuse patient records. The relationship of federal laws to state laws and regulations is also discussed. The materials, useful for persons involved in the fields of substance abuse treatment or prevention, list course objectives and limitations, and explain academic credit for course participation. The 13 course sessions are outlined in the manual, beginning with a pretest of major points in the federal confidentiality regulations and followed by presentations of specific aspects of the regulations. Participant exercises and samples are included, along with discussion of various confidentiality topics such as disclosures with and without patient consent and court orders. The appendix contains the test of the "Confidentiality of Alcohol and Drug Abuse Patient Records, Federal Law Title 42-Public Health." (NRB)

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ED209605

PARTICIPANT MANUAL

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

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Official interpretations of "Confidentiality of Alcohol and Drug Abuse Records," Regulations, 42 C.F.R. Part 2, may be obtained from the Office of the General Counsel, Department of Health and Human Services, Room 4A-53, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

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Introduction to the Course

PERSPECTIVE

In alcohol and drug abuse treatment programs, decisions must be made routinely on social, legal, and medical questions that are of profound personal importance to patients. Throughout the treatment process, the patients provide the program with confidential information that is potentially embarrassing or harmful if discretion is not exercised in determining when this information may be disclosed both within the program and outside of it.

On May 9, 1975, the Department of Health, Education, and Welfare (HEW) and the Special Action Office for Drug Abuse Prevention published (Federal Register 40 C.F.R. 20522) a notice of proposed joint rule creating a new Part 2 of Title 42 of the code of the Federal regulations governing the confidentiality of alcohol and drug abuse patient records. After comments, the new law became effective August 1, 1975.

These regulations were designed to provide a balance between the need for privacy and anonymity on the part of the parties and the need for pertinent information about these patients by other parties. The protection provided by the regulations increases the effectiveness of medical and social institutions and makes treatment more attractive to potential patients by allowing them to remain anonymous and by protecting their treatment records from public scrutiny.

OVERVIEW

Purpose

The purpose of this course is to provide the participant with a general overview of the Federal laws and regulations pertaining to confidentiality of alcohol and drug abuse patient records. The relation of these Federal laws to existing State laws and regulations will be discussed but is not a major focus of the course.

Persons For Whom This Course Is Intended

The course can be given to anyone involved in the fields of substance abuse treatment or prevention. This broad population can be further categorized as:

- Those persons responsible for the establishment, maintenance, monitoring, or enforcement of confidentiality policies and procedures (e.g., Social Security Administration, administrative, legal, and supervisory personnel); and
- Those persons who experience the practical, everyday application of the confidentiality laws and regulations (e.g., counselors, medical records technicians, criminal justice and prevention personnel, health and hospital workers).

To promote a more balanced dialogue and a fuller exposure of the issues, any given training population should contain representatives from each of the above two categories.

Learning Objectives

At the end of this course, trainees will be able to:

- Demonstrate an understanding of Federal Law Title 42 Code of Federal Regulations Part 2 by adhering to appropriate Federal laws and regulations and interpreting them correctly with minimal expert assistance.
- Describe areas of the law where there is flexibility in interpretating and applying them.
- Articulate accurate information about relevant State laws that pertain to confidentiality of alcohol and drug abuse patient records.
- Make informed decisions about releasing and limiting the release of confidential client information and support those decisions by reference to appropriate Federal and State laws.
- Identify and describe several examples of recordkeeping systems that protect the confidentiality of client information.
- Identify (orally or in writing) the important ethical considerations involved in protecting a client's right to privacy.

Course Limitations

The trainers and participants should be aware of the following limitations:

- The course will not provide conclusive opinions and court decisions on every question and concern.
- It will not resolve all of the conflicts that may arise between the State and Federal laws and regulations.
- Individual staff members and programs should not take the course as a substitute for seeking expert legal counsel for interpretation of the laws and regulations.
- A program should not use the course as the main source of information in developing program guidelines. (A program should follow up with the State training support person and legal counsel to review guidelines.)
- This course is not a substitute for on-going staff development sessions on the issues surrounding confidentiality.
- It is not intended that this course be offered to patients. Each program must develop its own educational mechanism for informing patients of their responsibilities and rights in this matter.

Academic Credit

This course has been approved by the American Council on Education for academic credit. Students have received up to two academic credit hours from various colleges and universities for participation in this course. Medical records associations in Rhode Island and Oklahoma have awarded 14 continuing education units to medical record technicians who took this 2-day confidentiality course.

Session 1

Pretest

Session 1

Pretest

Confidentiality Regulations Review Test

Following is a brief test of major points in the Federal confidentiality regulations covered by this course. The test is for self-assessment and is not comprehensive. After completing the test, check your answers. If you have missed any, you may wish to review the appropriate rules.

For the first 17 questions, circle the letter on your answer sheet to indicate whether each statement is true or false.

TRUE OR FALSE:

1. In the usual situation, if a minor applies for services to a treatment program in a State that requires guardian consent, the minor's written consent must be obtained before the fact of his application can be communicated to his or her guardian.

   T F

2. Patients in a drug abuse program can be required to carry program identification cards on and off program premises if the sole purpose is to assure positive identification of patients or correct recording of medication.

   T F

3. In general, consent for disclosure expires only after a formal request for revocation has been filed.

   T F

4. Federal confidentiality regulations specifically apply to programs that are funded in whole or in part by grants or contracts from the Federal government.

   T F

5. Disclosure of the identities of patients in narcotic maintenance and detoxification programs may be made to the Food and Drug Administration upon request by qualified personnel of the Food and Drug Administration for the purposes of audit verification.

   T F

6. Disclosures to medical personnel are authorized without patient consent if a genuine medical emergency exists and the information is needed for diagnosis and treatment.

T F

7. No supervisor or other person having authority over an undercover agent may knowingly permit such an agent to be or remain employed by or enrolled in any such program.

T F

8. An individual who is responsible for maintaining patient records is compelled to disclose patient information if served with a subpoena.

T F

9. One reason for which a program should release information to a central registry would be to discover if a patient is currently enrolled in more than one program for treatment.

T F

10. Patient records can be used for long-term evaluation studies.

T F

11. Third-party payers can maintain records on the identity of individuals in treatment programs.

T F

12. Consent forms containing false information are valid as long as the eight items required by law are included and reasonable care has been exercised by the program to assure the information contained therein is accurate.

T F

13. Confidentiality regulations do not apply to the exchange of information or records pertaining to a person relating to a period when such a person is or was subject to the Uniform Code of Justice when the exchange of information occurs exclusively within the Armed Forces or within those components of the Veterans Administration furnishing health care to veterans or between such components of the Armed Forces.

T F

14. Authorized agents of the Drug Enforcement Administration have access to the clinical records of any patient in a narcotic maintenance or detoxification program that is registered under Rule 303(g) of the Controlled

Substance Act only if authorized by a court order in accordance with Subpart E.

T F

15. When State laws and regulations regarding the confidentiality of alcohol and drug abuse patient records conflict with any particular section of the Federal regulations, the Federal regulations should be followed.

T F

16. A former employee may release information about a client that is not contained in the client's records.

T F

17. Attorney Jones asked Program "X" for information regarding his client who is enrolled in the program. The program required that a consent form be signed by both the attorney and client. Is the program correct in following this procedure?

T F

MULTIPLE CHOICE:

The next 10 questions are multiple choice. Blacken the letter of your answer sheet to indicate the single best answer to each question.

18. Disclosure of information concerning a client should be accompanied by a notice which clearly states that it is illegal for the recipient to further disclose the information to another party. An exception to the prohibition against redisclosure exists when:

    a) the original client consent form includes a general authorization for the release of information.

    b) the recipient is an employment agency which received the client's consent that explicitly authorized redisclosure of the information to potential employers for the purpose of securing employment for the client.

    c) the recipient is an evaluation specialist who reports summary data that cannot be traced to an individual.

    d) none of the above

19. Disclosures to a central registry should include information with respect to any patient:

    a) when he or she is applying for treatment

    b) when treatment is terminated

c) when the type or dosage of drugs is changed

d) all of the above

20. A court may authorize disclosure of patient records for the investigation or prosecution of a patient if he is believed to have been involved in:

a) rape

b) burglary

c) drunken driving

d) none of the above

21. When a program is acquired by another program and the patients have not consented to the transfer of their records, the records should be:

a) Sealed in envelopes, marked and labeled with name of the program, and stored for the required period, if their retention is required by State law; otherwise, they should be cleared for patient identity information or destroyed

b) released to the patients

c) stored indefinitely

d) transferred, since Federal regulations do not require patient consent for the transfer of records

22. An evaluation agency, having legally received patient data for analysis, may release information on specific individuals:

a) under a court order requiring disclosure

b) with written permission from the patient to redisclose

c) either of the above

d) none of the above

23. Even though written consent has been given by a patient to disclose information, the program director may legally refuse to disclose the information if:

a) the employer has previously denied promotions to individuals while in treatment

b) the information to be released appears to have little bearing on the job involved

c) both of the above

d) none of the above--the director cannot refuse a client's request to release information

24. Which of the following items is not required on a written consent form?

a) date on which consent is signed

b) extent or nature of information to be disclosed

c) purpose or need for disclosure

d) signature of staff member making disclosure

25. In a nonemergency situation, information about a patient may be given to his or her family:

a) if, in the judgment of the person responsible for treatment, disclosure will be helpful to the patient

b) if legal counsel for the family applies in writing for information about specific events claimed to reflect inappropriate treatment

c) only when formal written consent has been given by the patient

d) whenever the patient and family members are together

26. Because all situations requiring disclosure without consent cannot be anticipated, provision is made for exceptions benefiting the patient. Such disclosures may be made only at the discretion of:

a) a regularly constituted committee of at least five members of the treatment center staff

b) the director or his designated representative responsible for the patient records

c) the patient's doctor and the patient's attorney

d) none of the above

27. You were convicted last year and fined $500 for improperly releasing the name of a patient in your alcohol treatment program. You have just been found guilty of failing to maintain proper security of patients' records in your drug abuse treatment program:

a) the judge can fine you up to $500

b) the judge can fine you up to $5,000

c) the judge may impose imprisonment under the felony clause of the regulations

d) none of the above

Pretest Answer Sheet

TRUE/FALSE

1. T F
2. T F
3. T F
4. T F
5. T F
6. T F
7. T F
8. T F
9. T F
10. T F
11. T F
12. T F
13. T F
14. T F
15. T F
16. T F
17. T F

MULTIPLE CHOICE

18. A B C D
19. A B C D
20. A B C D
21. A B C D
22. A B C D
23. A B C D
24. A B C D
25. A B C D
26. A B C D
27. A B C D

Federal Regulations Key to Pretest

QUESTION NUMBER	FEDERAL REGULATIONS
1	2.15
2	2.20
3	2.31
4	2.12
5	2.55
6	2.51
7	2.19
8	2.61
9	2.34
10	2.53
11	2.37
12	2.31
13	2.1 and 2.12(b)
14	2.55
15	2.23
16	2.22
17	2.35
18	2.32
19	2.34
20	2.65
21	2.21
22	2.53 and 2.56
23	2.38
24	2.31
25	2.36
26	2.40(a)
27	2.14

NOTE:

It is necessary for the trainer to state the section of the Federal regulations in responding to any questions that are raised by the trainees. This will enable the trainees to know the section of the regulations and to review it subsequently.

Session 2

Subpart A
Introductory Statement
Rules 2.1-2.7

Session 2
Subpart A—Introductory Statement—Rules 2.1-2.7

§2.1 Statutory Authority--Drug Abuse
§2.2 Statutory Authority--Alcohol Abuse
§2.4 General Purposes
§2.6 Administration and Enforcement in General
§2.7 Reports of Violations

Learning Objectives

This session deals with the general provisions of the Federal regulations. At the end of this session, the participants should have an understanding of the statutory authority for the Federal laws on confidentiality, specifically:

- An overview of the statutory authority for the Federal laws on drug abuse (Rule 2.1).
- An overview of the statutory authority for the Federal laws on alcohol abuse (Rule 2.2).
- Comprehension of the general purpose and policy objectives of the Federal laws and rules (Rule 2.4).
- Understanding of the administration and enforcement of the Federal laws and regulations (Rule 2.6).
- Insight into the current processes for handling violations of the Federal and State laws and regulations.

§2.1: STATUTORY AUTHORITY--DRUG ABUSE

RULE

(a) Statutory provisions effective May 14, 1974. Insofar as the provisions of this part pertain to any program or activity relating to drug abuse education, training, treatment, rehabilitation, or research, such provisions are authorized under section 408 of Pub. L. 92-255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) as amended by section 303 of Pub. L. 93-282 (88 Stat. 137). That section reads as follows:

§408. Confidentiality of patient records.

(a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (c), be confidential and be disclosed only for the purposes

and under the circumstances expressly authorized under subsection (b) of this section.

(b)(1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) The prohibitions of this section do not apply to any interchange of records--

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense....

(g) As amended, this section now stipulates that the Secretary of Health, Education, and Welfare shall prescribe regulations to carry out the purposes of this section....

* * *

(Note: The next subsection of this Rule, subsection (h), was superceded by Public Law 94-581, Title I, f111(c)(4), October 21, 1976. See 21 USCA 1175.)

DISCUSSION

The Federal regulations protect the privacy of the client and confidentiality of the records of patients receiving drug abuse treatment, referral, education, training, and research. The regulations cover any information or record whether or not such record is recorded. Thus, Rules 2.1 and 2.2 prohibit the disclosure and release of patient information without the prior written consent of the patient to whom the record pertains. Exceptions to this prohibition are detailed in this rule.

Points to Remember

- The Federal regulations must be followed by any individual or program involved in drug abuse treatment, referral, education, training, and research, and, in general, any drug abuse prevention function.
- Prior written consent of the client must be secured before any information pertaining to a client or patient can be released.
- Exceptions to the prohibition against releasing information without the prior written consent of the patient that are referred to in Rule 2.1 are:
  - to medical personnel to respond to a bona fide medical emergency.
  - to qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation. However, such personnel would be prohibited from disclosing any information or reports that identify directly or indirectly patient identities in any form or manner. This requirement must be complied with even if the individual has official status or is a State agency.
  - if disclosure is authorized by an appropriate court order of a court of competent jurisdiction. The specific requirements for

securing and granting of court orders must be in accordance with Rules 2.61, 2.62, 2.63, and 2.64.

Note that 21 U.S.C. 1175(h) and 42 U.S.C. 4582(h) dealing with the relationship to the Veterans Administration and confidentiality of alcohol and drug abuse patient records have been superseded by 38 U.S.C. 4-131, et seq. 38 U.S.C. 4132 and 4134, read together, provide that the Veterans Administration is required to prescribe regulations protecting the confidentiality of its alcohol and drug abuse patient records and that the regulations prescribed are, to the extent practicable, to be consistent with 42 C.F.R. Part 2, the U.S. Department of Health, Education, and Welfare Regulations. Thus, the effect of 42 C.F.R. Section 2.12(b) Armed Forces and Veterans Administration must be considered in light of (and may be modified by) the requirements of 38 U.S.C. 4131, et seq., and whatever regulations may ultimately be promulgated under the provisions.

§2.2: STATUTORY AUTHORITY--ALCOHOL ABUSE

RULE

Insofar as the provisions of this part pertain to any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or reserach, such provisions are authorized under section 333 of Pub. L. 91-616, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. 4582), as amended by section 122(a) of Pub. L. 93-282, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974 (88 Stat. 131). As so amended, that section reads as follows:

CONFIDENTIALITY OF RECORDS

SEC. 333.(a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b)(1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) The prohibitions of this section do not apply to any interchange of records--

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary *are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith....*

* * *

(Note: The next subsection of this Rule, subsection (h), was superceded by Public Law 94-581, Title 1, Section 111(c)(4), October 21, 1976. See 42 UCSA 4582.)

DISCUSSION

Exceptions to this prohibition detailed in the rule permit disclosure whether or not the patient signs a written consent:

- to medical personnel to the extent necessary to respond to a bona fide medical emergency where the patient's health and safety is in question.
- to qualified personnel for the sole purpose of conducting scientific research, management, financial and program audits, or program evaluation. It is important that the personnel having access to such patient-identifying information not identify directly or indirectly patients in any report resulting from such research, audit, monitoring, or evaluation.
- if authorized by an appropriate order of a court of competent jurisdiction, an order shall be granted after an application showing good cause and no possible injury to the patient or the physician-patient relationship as a result of the disclosure.

Points to Remember

- The prohibitions of this rule and the Federal confidentiality laws will continue to apply to records of an alcohol and drug abuse patient even if that patient has terminated his or her relationship with the treatment program.
- The Federal regulations must be followed by any individual or program involved in drug abuse treatment, referral, education, training, and research, and, in general, any drug abuse prevention function.
- Prior written consent of the client must be secured before any information pertaining to a client or patient can be released.
- Exceptions to the prohibition against releasing information without the prior written consent of the patient are referred to in Rule 2.1.
- The effect of 38 U.S.C. 4131, et seq. 38 U.S.C. 4132 and 4134, read together, is to require the Veterans Administration to establish rules and regulations that will be similar to and consistent with 42

C.F.R. Part 2 pertaining to the patient records of alcohol and drug abuse patients.

- Note that the confidentiality requirements of Rules 2.1 and 2.2 of these regulations are identical for alcohol and drug abuse treatment, referral, rehabilitation, training, education, prevention functions, and research. Thus, any subsequent rules and regulations pertain to both alcohol and drug abuse functions.

§2.4: GENERAL PURPOSES

RULE

(a) Policy objectives. The purpose of the regulations set forth in this part is to implement the authorizing legislation in a manner that, to the extent practicable, takes into account two streams of legal thought and social policy. One has to do with enhancing the quality and attractiveness of treatment systems. The other is concerned with the interests of patients as citizens, most particularly in regard to protecting their rights of privacy. Within each stream there are cross-currents, and it should come as no surprise that areas of turbulence are to be found at their confluence.

(b) Limited purpose. The regulations contained in this part are not intended to direct the manner in which substantive functions, such as research, treatment, and evaluation, should be carried out, but rather to define the minimum requirements for the protection of confidentiality of patient records which must be satisfied in connection with the conduct of those functions in order to carry out the purposes of the authorizing legislation. This does not mean that observance of only the minimum legal requirements is always the wisest course, but in framing these regulations, allowance has necessarily been made for a diversity of emphasis and approach in the many different jurisdictions and by the great variety of public and private agencies which must find a way to function within the limits here prescribed.

* * *

DISCUSSION

The Federal regulations on confidentiality of alcohol and drug abuse patient records should enhance the quality and attractiveness of the various treatment programs and activities. The regulations are supportive of efforts to safeguard the interests and privacy of each client or patient by providing an orderly framework for protection of the rights of alcohol and drug abuse clients and patients.

Points to Remember

- The Federal regulations do not specify how drug abuse treatment should occur; rather, they provide minimum standards and requirements for protection of the confidentiality of alcohol and drug abuse patient records.
- Programs and individuals in the alcohol and drug abuse field can develop their own standards providing those fulfill the minimum Federal requirements of 42 C.F.R. Part 2.
- Observance of these Federal regulations is an ethical as well as a legal responsibility of each staff member and program involved in an alcohol or drug abuse function.
- Priority should be given to protection of the interests of patients as citizens, and particularly to the protection of each patient's right to privacy and confidentiality.

§2.6: ADMINISTRATION AND ENFORCEMENT IN GENERAL

RULE

It is not contemplated that any particular agency will be set up specifically to enforce compliance with this part. Programs which receive Federal grants may be monitored for compliance with this and other applicable Federal law as an incident to the grant administration process. Similarly, FDA inspections of methadone programs will include inspection for compliance with this part, which is incorporated by reference in the methadone regulation (21 CFR 310.505).

DISCUSSION

No particular agency will be set up to enforce compliance. However, several Federal agencies will provide oversight and inspection in the form of:

- NIDA/NIAAA staff site visits
- Federal fiscal and program audits
- FDA inspection of methadone programs
- U.S. Attorney's office.

Points to Remember

- Programs should expect that the Federal agencies, in particular NIDA and NIAAA, will monitor compliance with 42 C.F.R. Part 2, Regulations on Confidentiality of Alcohol and Drug Abuse Patient Records.

- Programs will be held accountable for failure to comply with the Federal regulations on confidentiality.
- Compliance will be ensured by other means; e.g., through monitoring and evaluations of programs by State governments.

NOTE:

1. Programs should be cognizant of the trend to establish enforcement units at both the Federal and State levels.

2. NIDA Confidentiality Compliance Office. NIDA's Division of Community Assistance has initiated a new effort to centralize the Institute's handling of all matters relating to the rules on confidentiality of alcohol and drug abuse patient records.

For additional information, contact:

Mr. Paul Curtis/Ms. Sheila Gardner
NIDA
Program Investigation, Inspection,
and Compliance
Division of Community Assistance
5600 Fishers Lane, Room 9-03
Rockville, Maryland 20857
(301) 443-6780

3. NIAAA Confidentiality Compliance Office. NIAAA's Division of Special Treatment and Rehabilitation handles the Institute's work relating to the rules of confidentiality of alcohol and drug abuse patient records.

For additional information, contact:

Mr. Fleetwood Roberts
Deputy Chief, Special Projects Branch
Division of Special Treatment
and Rehabilitation
National Institute on Alcohol Abuse
and Alcoholism
5600 Fishers Lane, Room 11A02
Rockville, Maryland 20857
(301) 443-1374

§2.7: REPORTS OF VIOLATIONS

RULE

Any violation may be reported to the United States Attorney for the judicial district in which the violation occurs. Violations on the part of methadone programs may be reported to the regional offices of the Food and Drug Administration. Violations on the part of a Federal grantee or contractor may be reported to the Federal agency monitoring the grant or contract.

Points to Remember

- Any violation may be reported to the U.S. Attorney for your jurisdiction where the violation occurs.
- Violations may be reported also to the FDA in the case of methadone programs.
- Violations from a Federal grantee or contractor may be reported to the Federal agency funding the grantee or contractor.

NOTE:

1. The trend is for Federal and State agencies to establish units that will be responsible for dealing with violations and complaints on confidentiality of drug and alcohol abuse patient records.
2. NIDA and the NIAAA have established units to respond to reports of violations.

For additional information, contact:

Mr. Paul Curtis/Ms. Sheila Gardner
NIDA
Program Investigation, Inspection,
  and Compliance
Division of Community Assistance
5600 Fishers Lane, Room 9-03
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Session 3

Subpart B
General Provisions
Rules 2.11-2.15

Session 3

Subpart B—General Provisions—Rules 2.11-2.15

§ 2.11 Definitions and Usages
§ 2.12 Applicability
§ 2.13 General Rules Regarding Confidentiality
§ 2.14 Penalty for Violations
§ 2.15 Minor Patients

Introductory Statement

This subpart of the Federal regulations deals with general provisions which pertain to the issues of definition and usages, applicability of confidentiality rules, general rules regarding confidentiality, penalty for violations, and minor patients.

Learning Objectives

At the end of this session, the participant should be able to:

- Understand the definitions and usages of terms (Rule 2.11) pertaining to confidentiality of alcohol and drug abuse patient records.
- Correctly apply the confidentiality rules to individuals and programs involved in activities related to substance abuse (Rule 2.12).
- Comprehend the general rules (Rule 2.13) regarding confidentiality as it relates to:
    - Civil, criminal, administrative, or legislative proceedings
    - Unconditional compliance
    - Scope of information covered, whether oral or written
    - Crimes on the premises or against program personnel
    - Implicit and negative disclosures
    - Inpatients and residents of treatment facilities.
- Know the process and application of the penalty (Rule 2.14).
- Understand the rules on the treatment of minors (Rule 2.15).

§ 2.11: DEFINITIONS AND USAGES

RULE

(a) Authorizing legislation. The term "authorizing legislation" means section 408 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) and section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582), as such sections may be amended and in effect from time to time.

(b) Construction of terms. The definitions and rules of construction set forth in this section are applicable for the purposes of this part. To the extent that they refer to terms used in the authorizing legislation, they are also applicable for the purposes of such legislation.

(c) Alcohol abuse. The term "alcohol abuse" includes alcoholism.

(d) Drug abuse. The term "drug abuse" includes drug addiction.

(e) Diagnosis and treatment. The terms "diagnosis" and "treatment" include interviewing, counselling, and any other services or activities carried on for the purpose of or as an incident to diagnosis, treatment, or rehabilitation with respect to drug abuse or alcohol abuse, whether or not conducted by a member of the medical profession.

(f) Program.

(1) The term "program", when referring to an individual or organization, means either an individual or an organization furnishing diagnosis, treatment, or referral for alcohol abuse or drug abuse....

(g) Program evaluation. The term "program evaluation" means an evaluation of--

(1) The effectiveness, efficiency, compliance with applicable therapeutic, legal, or other standards, or other aspects of the performance, of a program as defined in paragraph (f)(1) of this section, or

(2) The validity, effectiveness, efficiency, practicability, or other aspects of the utility or success of a program in the sense defined in paragraph (f)(2) of this section.

(h) Program director. The term "program director" in the case of a program which is an individual means that individual, and in the case of a program which is an organization, the individual, if any, who is the principal, or, in the case of organizations consisting of partners or under the control of a board of directors, board of trustees or other governing body, the individual designated as program director, managing director, or otherwise vested with executive authority with respect to the organization.

(i) Patient. The term "patient" means any individual (whether referred to as a patient, client, or otherwise) who has applied for or been given diagnosis or treatment for drug abuse or alcohol abuse and includes any individual who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug or alcohol abuse preliminary to a determination as to eligibility to participate in a treatment or rehabilitation program.

(j) Patient identifying information. The term "patient identifying information" means the name, address, social security number, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a patient identifying number assigned by a program....

(n) Qualified service organization. The term "qualified service organization" means a service organization which has entered into a written agreement with a program pursuant to which the service organization--

(1) acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the program about patients in the program, it is fully bound by the provisions of this part;

(2) undertakes to institute appropriate procedures for safeguarding such information, with particular reference to patient identifying information; and

(3) undertakes to resist in judicial proceedings any efforts to obtain access to information pertaining to patients otherwise than as expressly provided for in this part.

(o) Records. The term "records" includes any information, whether recorded or not, relating to a patient, received or acquired in connection with the performance of any alcohol abuse or drug abuse prevention function, whether such receipt or acquisition is by a program, a qualified service organization, or any other person.

(p) Communications not constituting disclosure. The following types of communications do not constitute disclosures of records:

(1) Communications of information within a program between or among personnel having a need for such information in connection with their duties.

(2) Communications between a program and a qualified service organization of information needed by the organization to perform its services to the program.

(3) Communications of information which includes neither patient identifying information nor identifying numbers assigned by the program to patients....

(s) Third party payer. The term "third party payer" means any organization (or person acting as agent or trustee for an organization or fund) which pays or agrees to pay for diagnosis or *treatment furnished or to be furnished to a particular individual, where such payment or agreement to pay is on the basis of an individual relationship between the payer and the patient (or a member of the patient's family in the case of self-and-family insurance coverage or similar arrangements) evidenced by a contract, an insurance policy, a certificate of membership or participation, or similar documentation.*

(t) Funding source. The term "funding source" means any individual or any public or private organization, including any Federal, State, or local governmental agency, which makes payments in support of a program. A funding source is not, as such, a third party payer, even where its payments are based directly or indirectly on the program's patient load with or without respect to specified categories of eligible persons....

* * *

DISCUSSION

These definitions and usuages provide clarity and consistency for the reader in understanding the meaning of the regulations.

Points to Remember

- It is advisable that the reader refer to and use the language and its intent in clarifying and explaining any section of these Federal regulations on confidentiality of alcohol and drug abuse patient records.
- The regulations in Rule 2.11(i) define the term "patient" to include individuals who meet the definition, whether referred to as patients, clients, participants, enrollees, residents, or otherwise.
- The definition of the word "record" in Rule 2.11(o) denotes that information, whether or not recorded, and all recorded information relating to and acquired in connection with providing services in alcohol and drug abuse, must be kept confidential.
- Also note that:
    1. Communication among treatment staff having a need for such information does not constitute a disclosure. However, programs have an affirmative duty to limit patient-identifying information and communication about clients to those staff who have a real need for the information. For this reason, a janitor would not normally be allowed access to patient-identifying information.
    2. Programs will not violate the Federal regulations 42 C.F.R. Part 2 by releasing any information on clients where such release does not explicitly or implicitly identify any individual as an alcohol and or drug abuse patient. Thus, statistical and

evaluation progress reports required by funding sources or by any third parties are releasable if no patient identifying information is implied or directly disclosed.

§2.12: APPLICABILITY

RULE

(a) In general. Except as provided in paragraph (b) of this section, this part applies to records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any alcohol abuse or drug abuse prevention function--

(1) Which is conducted in whole or in part, whether directly or by grant, contract, or otherwise, by any department or agency of the United States.

(2) For the lawful conduct of which in whole or part any license, registration, application, or other authorization is required to be granted or approved by any department or agency of the United States.

(3) Which is assisted by funds supplied by any department or agency of the United States, whether directly through a grant, contract, or otherwise, or indirectly by funds supplied to a State or local government unit through the medium of contracts, grants of any description, general or special revenue sharing, or otherwise, or

(4) Which is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program conducting such function, or by a way of tax-exempt status for such program.

(b) Armed Forces and Veterans' Administration.

(1) The provisions of this part do not apply to any interchange, entirely within the Armed Forces, within those components of the Veterans' Administration furnishing health care to veterans, or between such components and the Armed Forces, of records pertaining to a person relating to a period when such person is or was subject to the Uniform Code of Military Justice.

(2) Except as provided in paragraph (b)(1) of this section, this part applies to any communication between any person outside the Armed Forces and any person within the Armed Forces.

(3) Except as provided in paragraph (b)(1) of this section, this part applies, insofar as it pertains to any drug abuse prevention function, to any communication between any person outside those

components of the Veterans' Administration furnishing health care to veterans and any person within such components, until such date as the Secretary of Health, Education and Welfare exercises his authority (conferred by an amendment effective June 30, 1975) to prescribe regulations under section 408 of Pub. L. 92-255 (21 U.S.C. 1175). After such date, this part applies thereto to such extent as the Administrtor of Veterans' Affairs, through the Chief Medical Director, by regulation makes the provisons of this part applicable thereto.

(4) Except as provided in paragraph (b)(1) of this section, this part applies, insofar as it pertains to any alcohol abuse prevention function, to any communication between any person outside those components of the Veterans' Administration furnishing health care to veterans and any person within such components, to such extent as the Administrator of Veterans' Affairs, through the Chief Medical Director, by regulation makes the provisions of this part applicable thereto.

(c) Period covered as affecting applicability. The provisions of this part apply to records of identity, diagnosis, prognosis, or treatment pertaining to any given individual maintained over any period of time which, irrespective of when it begins, does not end before March 21, 1972, in the case of diagnosis or treatment for drug abuse or before May 14, 1974, in the case of diagnosis or treatment for alcohol abuse.

(d) Applicability determined by nature and purpose of records. The applicability of the provisions of this part is determined by the nature and purpose of the records in question, and not the status or primary functional capacity of the recordkeeper.

* * *

DISCUSSION

The provisions of this rule have broad application to individuals and programs providing any alcohol or drug abuse function, whether the financial support for such activity is received directly or indirectly through a Federal government entity. Ultimately, the application of the Federal regulations on confidentiality of alcohol and drug abuse patient records will be determined by the nature, function, and purpose of the records in question and not solely by the status or primary functional capacity of the program and entity which maintains the records.

Points to Remember

- Tax-exempt corporations and/or entities are covered by Rule 2.12 (a)(4), which follows the doctrine stated in McGlotten vs. Connally, 338 F. Supp. 448 (D.C. D.C., 1972), in which it was held that the deductible status of contributions to an organization constitutes "Federal financial assistance" within the meaning of Section 601 of the 1964 Civil Rights Act (42 U.S.C. 2000d). See, also, Green vs. Connally, 330 F. Supp. 1150 (D.C. D.C., 1971) aff'd sub. nom. Coit vs. Green, 404 U.S. 997, 92 S. Ct. 564, 30 L. Ed. 2d 550 (1971).

- Programs that are assisted by funds supplied by any department or agency of the United States Government, whether directly by a grant or contract or otherwise, or indirectly by funds supplied to the State or local government by an United States agency or department, must comply with the Federal confidentiality regulations.

- Although this rule does not specifically refer to private organizations, it is clear that such organizations are covered by the regulations if they receive direct or indirect Federal assistance and they maintain records otherwise covered by this part.

- It should be noted that the applicability of the regulations is determined ultimately by the nature and purpose of the records in question and not by the status or basic function and capacity of the recordkeeper (see Rule 2.12(d)).

- Nonprofit and tax-exempt organizations, programs, hospitals, and other entities including the criminal justice system (i.e., police, corrections, law enforcement agencies), must comply with the Federal regulations on confidentiality of alcohol and drug abuse patient records, 42 C.F.R. Part 2.

- Note that 21 USC 1175(h) and 42 USC 4582(h) (dealing with Veterans Administration regulations on confidentialty of alcohol and drug abuse patient records) have been superseded by 38 USC 4131, et seq. 38 USC 4132 and 4134, read together, provide that the Veterans Administration is to prescribe regulations protecting the confidentiality of its alcohol and drug abuse patient records and that these regulations are, to the extent practicable, to be consistent with 42 CFR Part 2, the HEW regulations. Thus, the effect of 42 CFR 2.12(b) must be considered in light of (and may be modified by) the requirements of 38 USC 4131, et seq., and whatever regulations may ultimately be promulgated under those provisions.

§2.13: GENERAL RULES REGARDING CONFIDENTIALITY

RULE

(a) In general. Records to which this part applies shall be confidential and may be disclosed only as authorized by this part, and may not otherwise be divulged in any civil, criminal, administrative, or legislative proceeding conducted by any Federal, State, or local authority, whether such proceeding is commenced before or after the effective date of this part.

(b) Unconditional compliance required. The prohibition upon unauthorized disclosure applies irrespective of whether the person seeking disclosure already has the information sought, has other means of obtaining it, enjoys official status, has obtained a subpoena, or asserts any other justification or basis for disclosure not expressly authorized under this part.

(c) Information covered by prohibition. The prohibition on unauthorized disclosure covers all information about patients, including their attendance or absence, physical whereabouts, or status as patients, whether or not recorded, in the possession of program personnel, except as provided in paragraph (d) of this section.

(d) Crimes on program premises or against program personnel. Where a patient commits or threatens to commit a crime on the premises of the program or against personnel of the program, nothing in this part shall be construed as prohibiting personnel of the program from seeking the assistance of, or reporting such crime to, a law enforcement agency, but such report shall not identify the suspect as a patient. In any such situation, immediate consideration should be given to seeking an order under Subpart E of this part to permit the disclosure of such limited information about the patient as may be necessary under the circumstances.

(e) Implicit and negative disclosures prohibited. The disclosure that a person (whether actual or fictitious) answering to a particular description, name, or other identification is not or has not been attending a program, whether over a period of time or on a particular occasion, is fully as much subject to the prohibitions and conditions of this part as a disclosure that such a person is or has been attending such a program. Any improper or unauthorized request for any disclosure of records or information subject to this part must be met by a noncommittal response.

(f) In-patients and residents. The presence of any in-patient in a medical facility or resident in a residential facility for the treatment of drug or alcohol abuse may be acknowledged to callers and visitors with his written consent. Without such consent, the presence of any in-patient or resident in a facility for the treatment of a variety of conditions may be acknowledged if done in such a way as not to indicate that the patient is being treated for drug or alcohol abuse.

* * *

DISCUSSION

The prohibition of unauthorized disclosure applies to an individual, program, or State or Federal entity, even if the person, agency, or entity seeking the disclosure:

- Already has the information in its possession and records;

- Had other means of obtaining the information sought;

- Has obtained a subpoena (as will be discussed in Rule 2.61, a subpoena cannot and does not compel disclosure of the information sought. Individuals and programs must resist such a subpoena unless it is accompanied by a court order on disclosure of the record or is otherwise authorized); or

- Asserts other justification or official status for disclosure of the information. Such efforts at disclosure should be resisted unless such request is authorized by the Federal regulations, there is written consent from the client involved, or there is an appropriate court order from a court of competent jurisdiction.

Finally, individuals and programs must be careful how they respond to inquiries about patients in their programs. A negative response might disclose sufficient patient-identifying information to violate the confidentiality of the alcohol and drug abuse patients.

Points to Remember

- Redisclosure of any information on patients of alcohol and drug abuse programs is prohibited unless specifically authorized by the regulations. It is necessary to resist disclosure of patient-identifying information at any civil, criminal, legislative, or administrative proceeding conducted by a local, State, or Federal authority.

- The information covered by the regulations includes every and any thing that will identify the client as a participant in your program, including but not limited to social security number, name, address, physical whereabouts or status as patients, and absence or attendance information (see Rule 2.13(c)).

- Rule 2.13(d), dealing with crimes that are committed on the program premises or against program personnel, is very important to staff and directors of alcohol and drug abuse programs. Often staff are threatened or even physically attacked, and patients might be involved in crimes on the premises of programs. The programs can respond to the crimes on the premises or against program personnel by reporting them to law enforcement authorities. However, it is important that in so doing the program does not disclose that the individual is a patient. In reality, it is difficult to report a crime in which a patient is involved without implying or inadvertently disclosing that the individual is a patient. Therefore, staff and programs should secure a court order under subpart E of the Federal regulations on confidentiality of alcohol and drug abuse patient records.

- Implicit and negative disclosures are prohibited in Rule 2.13(e). Thus, it is advisable for staff to be very careful in responding to verbal requests for information concerning a patient, even when

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people indicate they are spouses, children, or parents of the patient. The information that is given might result in disclosure of information prohibited under the regulations. For example, the phone rings: "Is John Doe there?" The response, "Yes, he is," would be a violation if it clearly implies patient status for that person, since Rule 2.13(c) states that patient-identifying information includes the whereabouts, attendance, and absence of the patient. Staff education on this and other parts of the regulations is critical to limit potential violations.

- Inpatients and residents in alcohol and drug abuse programs pose special problems because of the visitors and phone calls that are likely to come for them. It is advisable that programs secure the prior written consent of the client consistent with Rules 2.3l and 2.36 of the Federal regulations, before releasing any information to callers or admitting visitors. The experience of the author suggests that programs should obtain the written consent of the patient at the time of admission, and that it should be updated periodically. Hospital staffs will have to be particularly conscientious and innovative in establishing procedures to ensure confidentiality, especially where there is not a special ward for the treatment of alcohol and drug abuse patients that has well-established procedures on this subject.

§2.14: PENALTY FOR VIOLATIONS

RULE

(a) Penalty provided by law. Any person who violates any provision of the authorizing legislation or any provision of this part shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(b) Application to subsequent offenses. Where a defendant has committed one offense under either section authorizing this part or any provision of this part authorized by that section, any offense thereafter committed under the same section or any provision of this part authorized under that section shall be treated as a subsequent offense.

* * *

DISCUSSION

Any individual who violates the Federal confidentiality regulations will have committed a criminal violation in the form of a misdemeanor. Thus, the individual is liable for a fine but not a jail sentence, since the regulations specifically limit punishment for violations to a fine for the first and subsequent offenses.

One of the things to bear in mind is that, although this is a criminal statute, and any violation will result in a criminal sanction, the violation of an individual's confidentiality could expose the individual to a civil suit for damages by the person so affected.

Points to Remember

- Drug abuse and alcohol abuse are covered by separate statutes.
- Penalty for violation of any regulation in this statute is not more than $500 for the first offense and not more than $5,000 for each subsequent offense.
- A subsequent offense need not be identical to the first offense.
- This is a criminal statute, even though no jail term may be imposed.
- If the first offense is a violation of the alcohol statute, then the second violation of the alcohol statute will be a subsequent offense; but a violation of the drug abuse statute would be a first offense under the drug abuse statute.

§2.15: MINOR PATIENTS

RULE

(a) Definition of minor. The term "minor" means a person who has not attained the age of 18 years or, in a State where a different age is expressly provided by State law as the age at which a person ceases to be a minor, the age prescribed by the law of such State.

(b) Consent to disclosure in general. Except as provided in paragraph (c), where consent is required for any disclosure under this part, such consent in the case of a minor must be given by both the minor and his parent, guardian, or other person authorized under State law to act in his behalf, but any disclosure made after the patient has ceased to be a minor may be consented to only by the patient.

(c) Rule when State law authorizes treatment without parental consent. Whenever a patient, acting alone, has the legal capacity under the applicable State law to apply for and obtain such diagnosis, counselling, administration of medication, or other services as actually are or were provided to him by the program with respect to which he is or was a patient, any consent required for disclosure under this part may be given only by the patient, notwithstanding the fact that the patient may be a minor.

(d) Initial contacts. When a minor applies for services under circumstances other than those described in paragraph (c) of this section, the fact of such application may not be disclosed, except as an incident to a communication authorized under paragraph (f) of this section, without consent of the applicant, to the applicant's parent, guardian, or other person authorized under State law to act on behalf of the applicant. When such an applicant refuses consent, it must be explained to the applicant that, while he or she has the right (subject to the provisions of paragraph (f) of this section) to withhold such consent, the services applied for cannot be provided without it.

(e) Collection or attempted collection of payment for services. Where State law authorizes the furnishing of services to a minor without the consent of the minor's parent or guardian, no inquiry may be made of the parent's or guardian's financial responsibility, and no bill, statement, request for payment, or any other communication in respect of such services may be transmitted directly or indirectly to such parent or guardian, without the express written consent of the patient. Such consent may not be made a condition of the furnishing of services except in the case of a program which is not required by law, and does not in fact hold itself out as willing, to furnish services irrespective of ability to pay.

(f) Applicant lacking capacity for rational choice. When, in the judgment of a program director a minor applicant for services, because of extreme youth or mental or physical condition, lacks the capacity to make a rational decision on whether to consent to the notification of a parent or guardian, and the situation of the applicant poses a substantial threat to the life or physical well-being of the applicant or any other individual, and such threat might be reduced by communicating the relevant facts to a parent or guardian of the applicant, such facts may be so communicated by the program director or by program personnel authorized by the director to do so.

* * *

DISCUSSION

Treatment programs continue to admit minors for alcohol and drug abuse problems. It is necessary to understand that Rule 2.15 of the Federal regulations provides that the definition of a minor and that the rules and regulations for the treatment of minors for alcohol and drug abuse problems will be promulgated by the individual State. Each State can pass laws and institute regulations on the treatment of minors for alcohol and drug abuse problems that allow minor patients to receive drug and alcohol services without the consent of parent or guardian.

Where your particular State law permits a minor patient to receive services without the consent of parent or guardian, the program is prohibited from disclosing the presence of the minor to the parent without the minor's consent. Additionally, without such consent, the program is prohibited in Rule 2.15(e) from collecting or attempting to collect the cost of services from parents of the minor.

Programs should follow the requirements of Rule 2.15(f) for those minor patients lacking capacity for rational choice due to intoxication, substance abuse, or any other cause, whether it be for mental or physical condition or extreme youth. The program director may notify the parent or guardian and communicate such information nothwithstanding any State laws allowing a minor to receive treatment for alcohol and drug abuse problems without the consent of parent or guardian.

Points to Remember

- In the usual case, treatment of minor patients for alcohol or drug addiction requires that the parent of the patient consent to such treatment. However, this requirement has been changed by individual State laws that allow minors to receive either drug or alcohol treatment, or both forms of treatment services, without parental consent.

- All individuals and programs should contact their State authorities for alcohol and drug abuse to obtain clarification on the State laws and regulations pertaining to confidentiality of alcohol and drug abuse patient records.

    - In the usual case, treatment of minor patients for alcohol or drug addiction requires consent from both the patient and guardian.

    - Exceptions to this rule occur when State law authorizes treatment for minors without parental consent.

    - A minor's application usually cannot be communicated by a program to his or her parents without consent of the minor.

    - Where State law authorizes the furnishing of services to a minor without the consent of the minor's parent or guardian, no inquiry may be made of the parent or guardian of the patient's financial responsibility, and no bill, statement, request for payment, or any other communication in respect of such services may be transmitted directly or indirectly to such parent or guardian without the express, written consent of the minor patient. Such express, written consent may not be made a condition of the furnishing of services except in the case of a program that is not required by law and does not in fact publicize itself as willing to furnish services irrespective of ability to pay.

Exercise I: Development of a Qualified Service Organization Agreement, Rule 2.11

Problem: You are contracting with a medical laboratory to provide urinalysis for your substance abuse program. How will you ensure that the laboratory complies with 42 C.F.R. Part 2 regarding the confidentiality of drug and alcohol patient records?

Product: A completed qualified service agreement form, printed on newsprint.

Directions

1. Meet in your assigned small group. In order to enhance the group's work, choose an individual for each of these roles:

   Timekeeper: requires access to a watch or clock and willingness to keep group informed of remaining time.

   Recorder: requires legible handwriting and willingness to put group's produce on newsprint.

   Spokesperson: requires ability to present or clarify group's work to the rest of the course participants.

2. As a group, develop a qualified service agreement. Be sure to complete the form according to the items discussed during training thus far and the information provided in the problem statement above.

   Timekeeper: Allow 15 minutes to complete the task.

   Recorder: Print the group's qualified service agreement form on newsprint.

   Spokesperson: Bring newsprint back to main meeting area; display; be prepared to present/clarify work. You will have approximately 3-4 minutes to present.

Trainees are urged to seek help, if needed, from the training staff.

SAMPLE
Qualified Service Organization Agreement

Whereas the ____ provides
Name of Service Organization

____ to the ______________
Type of Service Provided by Organization of Program   Name of Program

and where the ______________________ needs the following information
Name of Service Organization

____
Specify Information

in order to provide its services to the program; and whereas the disclosure of this information is governed by the Federal regulations on the confidentiality of alcohol and drug abuse patient records 42 C.F.R. Part 2. Therefore the

______________________ and the ______________ entered into a quali-
Name of Service Organization   Name of Program

fied service organization agreement whereby the ______________________
Name of Service Organization

1. *Acknowledges that in receiving, storing, or otherwise dealing with any information from the program about the patients in the program that is fully bound by the requirements of 42 C.F.R. Part 2 and "any relevant state laws."

2. Agrees that it will institute appropriate procedures for safeguarding such information, particularly patient-identifying information; and

3. Agrees that it will resist in judicial proceedings any efforts to obtain access to any information pertaining to patients otherwise than expressly provided for in 42 C.F.R. Part 2 and any relevant State laws.

4. The (Service Organization) RECOGNIZES THAT ANY UNAUTHORIZED DISCLOSURE OF PATIENT INFORMATION IS A FEDERAL CRIMINAL OFFENSE PUNISHABLE BY A FINE OF NOT MORE THAN $500.00 IN THE CASE OF A FIRST OFFENSE AND NOT MORE THAN $5,000.00 IN THE CASE OF EACH SUBSEQUENT OFFENSE.

Executed this ______________ day of ______________, 19 __.

____
Signature of Service Organization Representative

____
Signature of Authorized Program Representative

Exercise II: Parent Requesting Confidential Information on Minors, Rule 2.15

Problem

On November 1, 1977, a client came to the Swing Outpatient Methadone Clinic and requested that she be enrolled in the program. The client is 16 years old and lives with her parents. During the interview, the mother of the patient telephoned and asked the receptionist whether her daughter had enrolled in the program. The program staff is uncertain about the correct procedure to follow.

Products

1. A list of the confidentiality issues involved in this case study.

2. A list of critical information about the treatment program and the confidentiality of its patient records policies that should be given to new patients. (Newsprint B)

3. A group decision written as a statement that says either "The program SHOULD release (what) information to the parent," or "The program SHOULD NOT release (what) information to the parent." (Newsprint C)

4. A list of the procedures the clinic should implement to protect the confidentiality of the patient's records. (Newsprint D)

Directions

1. Meet in your assigned small group. Choose a timekeeper, recorder, and spokesperson.

   Timekeeper: Allow 15 minutes to complete the entire task. If desired, allocate a specific number of minutes for each product.

   Recorder: Prepare newsprint labeled "A," "B," "C," and "D" for each product. Print the group's work on each.

   Spokesperson: Be prepared to present/clarify work. Bring newsprint back to main meeting area; display. You will have approximately 5 minutes to present.

2. As a group, develop a list of the confidentiality issues that are involved in this case study. (Be careful not to spend too much time on this task.) Put the list on Newsprint A.

3. On Newsprint B, make a list of items that responds to this question:

   As a staff person, what kinds of information about the program and the way it handles the confidentiality of patient records should be given to a new patient to protect the confidentiality of the patient's records?

4. Discuss and then decide as a group whether the program should or should not release any information to the parent. On Newsprint C, write your conclusion regarding this decision.

5. List the procedures that you think the clinic should implement to protect the confidentiality of the patient's records. Post this list on Newsprint D.

Trainees are urged to seek help, when needed, from the training staff.

Exercise II: Parent Requesting Confidential Information on Minors, Rule 2.15

Participant Notes

A. CONFIDENTIALITY ISSUES INVOLVED

B. CRITICAL INFORMATION TO BE GIVEN NEW PATIENTS

C. DECISION: SHOULD ANY INFORMATION BE RELEASED TO THE MOTHER?

D. PROCEDURES THE CLINIC SHOULD IMPLEMENT

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Session 4

State Laws
Rule 2.23

Session 4
State Laws—Rule 2.23

§2.23 Relationship to State Laws

Learning Objectives

At the end of this session the participant should be able to:

- Understand Federal Rule 2.23 as it relates to the preemption and conflict of State and Federal laws.
- Identify areas where the State law is consistent as well as those where it is in conflict with the Federal law.

§ 2.23: RELATIONSHIP TO STATE LAWS

RULE

The enactment of the provisions of law authorizing this part was not intended to preempt the field of law covered thereby to the exclusion of State laws not in conflict therewith. If a disclosure permitted under the provisions of this part, or under a court order issued pursuant thereto, is prohibited under State law, nothing in this part or in the provisions of law authorizing this part may be construed to authorize any violation of such State law. No State law, however, may either authorize or compel any disclosure prohibited by this part.

* * *

DISCUSSION

Implicit in Rule 2.23 is the message that treatment programs must comply with existing State laws notwithstanding Title 42 C.F.R. Part 2 on confidentiality. This means that programs must follow State law requirements for reporting:

1. Child abuse, even if the individual involved is a patient in the program.
2. Crimes committed in violation of any criminal laws of the State. Where crimes are committed on the premises of the program or against program personnel, it is essential to follow the procedures for reporting crimes as outlined in Federal Rule 2.13(d).
3. Conditions specified in State law pertaining to health care; e.g., reporting of venereal disease.

Points to Remember

- Compliance is also required in other areas such as State laws pertaining to the treatment of minor patients. See Rule 2.15.

- State laws regulate the disposition of discontinued program records. The silence of Federal Rule 2.21 as to the specific number of years for retention of alcohol and drug abuse patient records allows the State to promulgate its own guidelines.

- Federal law has been held to preempt State law where the State law and regulation prohibit the Department of Health, Education, and Welfare's (DHEW) National Institute on Drug Abuse (NIDA), from reviewing and inspecting records of drug abuse patients. In a recent conflict, it was held that Article VI, Clause 2 of the United States Constitution requires disclosure of patient records for the limited purpose of an audit.

- Consistent with the Supremacy Clause of the United States Constitution, Article VI, Clause 2, when State law and the confidentiality regulations are in conflict, the confidentiality regulations supersede the applicable State law. 42 C.F.R. § 2.23 does not limit this supremacy of Federal law. Rather, it states that enactment of the provisions of law authorizing this part was not intended to preempt the field of law covered thereby to the exclusion of State laws not in conflict therewith. (Emphasis added.)

  Futhermore, the section adds that if a disclosure permitted under the provisions of this part, or under court order issued pursuant thereto, is prohibited under State law, nothing in this part or in the provisions of law authorizing this part may be construed to authorize any violation of such State law. (Emphasis added.) What this language means, in essence, is that, while the confidentiality regulations permit disclosures, they do not require disclosures and, thus, if a disclosure is prohibited by the regulations, no State law may either authorize or compel the disclosure. This result is consistent with the supremacy of the regulations over State law when the two are in conflict.

Session 5

General Provisions
Rules 2.16-2.24

Session 5
General Provisions—Rules 2.16-2.24

§2.16 Incompetent and Deceased Patients
§2.17 Security Precautions
§2.18 Extent of Disclosure
§2.19 Undercover Agents and Informants
§2.20 Identification Cards
§2.21 Disposition of Discontinued Program Records
§2.22 Former Employees and Others
§2.24 Relationship to Section 303(a) of Public Health Service Act and Section 502(c) of Controlled Substances Act

Learning Objectives

By the end of this session, the participant should be able to:

- Understand the application of the Federal rules on confidentiality to deceased patients (Rule 2.16 (b)(2)).
- Develop the specific steps that must be taken to ensure security of patient records (Rule 2.17).
- Comprehend measures to be taken to limit disclosure of information to the actual need for said disclosure (Rule 2.18).
- Devise guidelines to allow undercover agents and informants to be enrolled for treatment and to understand the distinction between Rule 2.19 and Rule 2.67, which permits the court to issue an order placing an undercover agent/informant in a program without the program's knowledge or consent.
- Develop appropriate guidelines for the identification of patients while they are enrolled in the program (Rule 2.20).
- Understand the Federal and State requirements for retention of records of substance abuse programs (Rule 2.21).
- Implement the minimum requirements for ensuring that former employees and others who have had access to patient records maintain the confidentiality of these records even after termination of their relationship with the program (Rule 2.22).
- Understand the relationship of the Federal preemption issue as it relates to Federal and State laws.
- Understand the overlapping relationship between 42 C.F.R. Part 2 and Rule 303(a) of the Public Health Service Act and Rule 502(c) of the Controlled Substances Act.

§2.16: INCOMPETENT AND DECEASED PATIENTS

RULE

(a) Incompetent patients other than minors. Where consent is required for any disclosure under this part, such consent in the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(b) Deceased patients.

(1) In general. Except as provided in paragraph (b)(2) of this section, where consent is required for any disclosure of this part, such consent in the case of records of a deceased patient may be given by an executor, administrator, or other personal representative. If there is no appointment of a personal representative, such consent may be given by the patient's spouse, or if none, by any responsible member of the patient's family.

(2) Vital statistics. In the case of a deceased patient, disclosures required under Federal or State laws involving the collection of death and other vital statistics may be made without consent.

* * *

DISCUSSION

The Federal regulations permit disclosure of information pertaining to an incompetent patient (a person adjudicated by a court as lacking the capacity to manage his or her own affairs), by a guardian or an individual duly authorized under existing State laws to act on the patient's behalf, including the giving of written consent for the release of the patient information. The written consent given by such guardian or duly authorized person should conform to the requirement for the release of patient information under Rule 2.31 of the Federal regulations.

Points to Remember

- The right to confidentiality of records of an alcohol or drug abuse patient continues even after the patient has died. Release of information pertaining to a deceased patient is prohibited without the prior written consent of an executor, administrator, spouse, or other personal representative of the patient.
- Consent for the release of records of an incompetent person may be given by the patient's legal guardian or other persons authorized under State law to act on the patient's behalf.

- Programs may release information on a deceased patient with the written consent of an executor, administrator, or other personal representative or, if there is no personal representative, with the consent of the deceased's spouse or, if there is none, a responsible family member.

§ 2.17: SECURITY PRECAUTIONS

RULE

(a) Precautions required. Appropriate precautions must be taken for the security of records to which this part applies. Records containing any information pertaining to patients shall be kept in a secure room, or in a locked file cabinet, safe, or other similar container, when not in use.

(b) Policies and procedures. Depending upon the type and size of the program, appropriate policies and procedures should be instituted for the further security of records. For example, except where this function is personally performed by the program director, a single member of the program staff should be designated to process inquiries and requests for patient information, and a written procedure should be in effect regulating and controlling access by those members of the staff whose responsibilities require such access, and providing for accountability.

* * *

DISCUSSION

It should be noted that the Federal regulations place an affirmative duty on the directors of programs to ensure that records pertaining to an alcohol and drug abuse patient are stored in a secure manner. Rule 2.17(a), Precautions Required, states that records containing any information pertaining to patients shall be kept in a locked file cabinet, safe, or similar container, when not in use. The program director is obliged to make sure records are not left on top of desks and patient information is stored in a secure room or container when this record is not being used.

Rule 2.17(b), Policies and Procedures, provides the program with flexibility for designing and preparing policies and procedures for the security of records specifically relevant to the type of treatment modality, the program size, and other necessary program characteristics; e.g., a treatment program in a prison.

Points to Remember

- Appropriate precautions should be taken at all times for the security of patient records.

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- Definite policies and procedures should be developed and maintained to ensure security of patient records.
- Access to patient records in a drug and alcohol program should be limited to those individual staff members who have a need for the information contained in said records.

§2.18: EXTENT OF DISCLOSURE

RULE

Any disclosure made under this part, whether with or without the patient's consent, shall be limited to information necessary in the light of the need or purpose for the disclosure.

* * *

Points to Remember

- As a general rule, only the information that is required to fulfill the expressed purpose or specific need should be disclosed--with or without the patient's consent.
- If a program considers it to be in the best interest of a client to limit or not disclose information requested pursuant to a valid consent of the patient, the program may refuse to disclose the information. However, the program should note that a court order could compel disclosure of the information withheld by the program.

§ 2.19: UNDERCOVER AGENTS AND INFORMANTS

RULE

(a) Definitions. As used in this section, §2.19-1, §2.67 and §2.67-1,--

(1) The term "undercover agent" means a member of any Federal, State, or local law enforcement or investigative agency whose identity as such is concealed from either the patients or personnel of a program in which he enrolls or attempts to enroll.

(2) The term "informant" means a person who, at the request of a Federal, State, or local law enforcement or investigative agency or officer, carries on observation of one or more persons enrolled in or employed by a program in which he is enrolled or employed, for the purpose of reporting to such agency or officer

information concerning such persons which he obtains as a result of such observation subsequent to such request.

(b) General prohibition. Except as otherwise provided in paragraph (c) of this section, or as specifically authorized by a court order granted under §2.67,--

(1) No undercover agent or informant may be employed by or enrolled in any alcohol or drug abuse treatment program;

(2) No supervisor or other person having authority over an undercover agent may knowingly permit such agent to be or remain employed by or enrolled in any such program; and

(3) No law enforcement or investigative officer may recruit or retain an informant with respect to such a program.

(c) Exceptions. The enrollment of a law enforcement officer in a treatment program shall not be deemd a violation of this section if (1) such enrollment is solely for the purpose of enabling the officer to obtain treatment for his own abuse of alcohol or drugs, and (2) his status as a law enforcement officer is known to the program director.

* * *

DISCUSSION

The Federal regulations and Rule 2.19 do not prohibit an undercover agent, policeman, or other law enforcement agent from enrolling in an alcohol or drug abuse treatment program for the sole purpose of receiving treatment for his or her own abuse of alcohol or drugs provided that his or her status as a law enforcement officer is made known to the program director at the time of admission for such treatment. Failure of the law enforcement individual to report such status will result in a violation of the Federal Regulations on Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

Points to Remember

- Undercover agents and informants are prohibited from being employed or enrolled as patients in a substance abuse program.
- No person in authority may permit employment or enrollment of undercover agents or informants in a drug or alcohol treatment program.
- Exceptions to the above rules exist where an undercover agent or law enforcement agent is enrolled solely to receive treatment and his or her status as an agent or officer is known to the program or an authorizing court order is obtained under Rule 2.67.

§2.20: IDENTIFICATION CARDS

RULE

(a) Required use prohibited. No program may require or request any patient to carry in his or her possession, while away from the program premises, an identification card or other form of identification which is issued by the program or which would tend to identify the bearer as a participant in it or any similar program.

(b) Conditions of voluntary use. Nothing in this section prohibits a program from issuing an identification card to a patient if the patient's counsellor or other authorized member of the program staff has explained to the patient that acceptance and use of the card is entirely voluntary and that neither an initial rejection nor a subsequent discontinuation of its use will in any way prejudice his or her record or standing in the program. In the case of any patient to whom an identification card or similar device was issued prior to the effective date of this section, or subsequent thereto in violation of this section, a counsellor or other authorized member of the program staff shall explain to the patient his right to turn it in without prejudice at any time.

(c) On-premises exemption. Nothing in this section prohibits a program from maintaining and using on its premises cards, photographs, tickets, or other devices, or using passwords or other information, to assure positive identification of patients, correct recording of attendance or medication, or for other proper purposes, as long as no pressure is brought on any patient to carry any such device when away from the program premises.

* * *

DISCUSSION

No drug treatment patient may be required to carry identification as a member of a program while the patient is off the premises.

If a patient has been issued an identification card prior to August 1, 1975, the patient must be told by the program that he or she has the right to turn in the card at any time.

A program is not prohibited from issuing an identification card to a patient if:

1. The patient's counselor has explained that use of the identification card is completely voluntary.
2. Refusal to use identification card will not damage the patient's record or status in the program.

Points to Remember

- Programs may not require that patients carry program identification cards when they are off the program premises.
- All patients may be required to carry identification cards while on the premises of the program to ensure positive identification of the patient. The program procedures should include retrieval of these identification cards before the patient leaves the program premises.
- The prohibition against identification cards does not prevent a program from issuing an identification card to a patient providing the following steps are followed:
    1. There is adequate proof of voluntary use of the identification card by the patient. The program staff will have to explain to the patient that its use is voluntary and there are advantages and disadvantages of its use off the premises.
    2. The program must explain to the patient that he or she is not required to carry such identification off the premises and that the practice of using such a card could be discontinued at any time by the patient.
    3. It is practical and desirable for the staff to secure written consent of the patient for the voluntary use of the identification off the premises.

§2.21: DISPOSITION OF DISCONTINUED PROGRAM RECORDS

RULE

(a) General rule. When a program discontinues operations or is taken over or acquired by another program, its records to which this part applies with respect to any patient may, with the written consent of that patient, be turned over to the acquiring program or, if none, to any other program specified in the patient's consent. Except as otherwise provided in this section, any records to which this part applies, but for the transfer of which patient consent is not obtained, shall be either completely purged of patient identifying information, or destroyed. If any effort to obtain consent for transfer is made, it shall be by means which minimize the likelihood of accidental or incidental disclosure to any third party of the patient's identity as such.

(b) Retention period. Where records are required by law to be kept for a specified period, and such period does not expire until after the discontinuation or acquisition of the program, and patient consent for their transfer is not obtained, such records shall be sealed in envelopes or other containers marked or labelled as follows: "Records of (insert name of program)

required to be maintained pursuant to (insert citation to law or regulation requiring that records be kept) until a date not later than December 31, (insert appropriate year)." The same procedure may be followed when it is determined to retain records for the period of any applicable statute of limitations.

(c) Custodial retention. Records marked and sealed in accordance with paragraph (b) of this section may be held by any lawful custodian, but may be disclosed by such custodian only under such circumstances and to such extent as would be permissible for the program in which they originated. As soon as practicable after the date specified on the label or legend required to be affixed pursuant to paragraph (b) of this section, the custodian shall destroy the records. In the case of any program terminated by reason of bankruptcy, the expense of compliance with this paragraph shall be an expense of administration of the bankrupt estate.

* * *

DISCUSSION

Termination of programs is of concern to many because funding patterns and priorities of funding sources change. The availability of funds for alcohol and drug abuse treatment and services continues to be scarce, resulting in the termination of many programs throughout the country. As these programs end, special attention must be given to compliance with Rule 2.21, which requires that when a program is taken over or discontinued or acquired by another program, its records may be turned over with the written consent of the patient(s) to the program or such program as the patient may specify.

Points to Remember

- In the event a program is terminated, the program could transfer the records to another program providing there is prior written consent.

- Without patient consent, records must be destroyed or cleared of patient-identifying information or, if records must be kept for a period according to law, they may be kept by any lawful custodian but must be destroyed after the date specified by this section.

- It is advisable for individuals and programs involved in alcohol and drug abuse treatment or functions to seek an opinion from the Single State Agency for alcohol and drug abuse about the length of the retention period for such records.

- Those treatment programs such as hospitals that are accredited by the Joint Commission on the Accreditation of Hospitals (JCAH) should comply with these requirements in addition to the State regulations.

§2.22: FORMER EMPLOYEES AND OTHERS

RULE

The prohibitions of this part on disclosure of patient records or information contained therein apply to all individuals who are personnel of treatment programs, researchers, auditors, evaluators, service organizations, or others having access to such records or information, and continue to apply to such individuals with respect to such records or information after the termination of their employment or other relationship to activity giving rise to such access.

* * *

DISCUSSION

The Federal regulations require that all former employees, part-time or full-time, and volunteers or student interns who have worked in an alcohol or drug abuse program refrain from disclosing any patient-identifying information even after termination of their employment. This prohibition embodied in Rule 2.22 should be strictly observed to avoid violations of the Federal regulations.

Each alcohol and drug abuse program should incorporate, as part of its personnel policies, rules, and procedures to be followed by staff, especially those staff who are leaving.

Points to Remember

- Programs should establish personnel policies to inform staff of these requirements at the time of hiring, during the course of employment, and at the time of termination.
- The terminating staff members should be advised in writing as well as orally that they must comply with the confidentiality regulations even after termination of employment with the program. This means that the terminated employee cannot disclose to anyone information on a patient without the prior written consent of the patient or other authorization.
- Programs should notify both current and terminated employees regarding the requirements of Rule 2.22.

§2.24: RELATIONSHIP TO SECTION 303(a) OF PUBLIC HEALTH SERVICE ACT AND SECTION 502(c) OF CONTROLLED SUBSTANCES ACT

RULE

(a) Research privilege description. In some instances, there may be concurrent coverage of a program or activity by the provisions of this part and by a regulation or other administrative action under section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c))....

* * *

DISCUSSION

Methadone programs may wish to refer to the methadone regulations of the Food and Drug Administration, 21 C.F.R. 291.505(g)(2), for the effect of 42 U.S.C. 242a(a) on methadone patient records.

Exercise III: Former Employee Compliance, Rule 2.22

Problem

A counselor in an alcohol and drug abuse outpatient clinic indicated that he or she will resign at the end of the month.

As Program Director, you are concerned about protecting confidentiality of the oral and written patient information to which this staff member has had access. Develop appropriate procedures to ensure confidentiality.

Products

1. A form that could be utilized to make sure that former employees comply with the confidentiality laws.
2. A policy and procedure for the implementation of this form.

Directions

1. Meet in your assigned small group. Choose a timekeeper, recorder, and spokesperson.

   Timekeeper: Since this is an open-ended evening meeting task, help the group establish a time limit and then complete the work on time.

   Recorder: Prepare one piece of newsprint showing the form. Prepare a separate piece of newsprint outlining the policy and procedure for implementing the form.

   Spokesperson: Be prepared to present/clarify your group's work. Bring the newsprint to the main meeting room; display. You will have approximately 10 minutes to present.

2. As a group, design the form that you would utilize to make sure that former employees comply with the confidentiality laws. Write this on newsprint.
3. Develop a policy and procedure for the implementation of this requirement, and, on a separate piece of newsprint, outline your work.

Trainees are urged to seek help, if needed, from the training staff. Remember that this is an evening exercise and may require special arrangements for assistance.

Session 6

Subpart C
Disclosures With Patient Consent

Session 6
Subpart C—Disclosures With Patient Consent

§ 2.31 Written Consent Required
§ 2.32 Prohibition on Redisclosure

Learning Objectives

At the completion of this session the participants should be able to:

- Draw up a valid consent form with all the necessary eight points stated in Rule 2.31.
- Understand how this consent form should be used in the release of patient information.
- Prepare the statement regarding the prohibition against redisclosure that is required in Rule 2.32.

§2.31: WRITTEN CONSENT REQUIRED

RULE

(a) Form of consent. Except as otherwise provided, a consent for a disclosure under this part must be in writing and must contain the following:

(1) The name of the program which is to make the disclosure.

(2) The name or title of the person or organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose or need for the disclosure.

(5) The extent or nature of information to be disclosed.

(6) A statement that the consent is subject to revocation at any time except to the extent that action has been taken in reliance thereon, and a specification of the date, event, or condition upon which it will expire without express revocation.

(7) The date on which the consent is signed.

(8) The signature of the patient and, when required under § 2.15, the signature of a person authorized to give consent under that section; or, when required under §2.16, the signature of a person authorized to sign under that section in lieu of the patient.

(b) Duration of consent. Any consent given under this subpart shall have a duration no longer than that reasonably necessary to effectuate the purpose for which it is given.

(c) Disclosure prohibited with deficient consent. No program may disclose any information on the basis of a consent form--

(1) which on its face substantially fails to conform to any of the requirements set forth in paragraph (a), of this section, or

(2) which is known, or in the exercise of reasonable care should be known, to the responsible personnel of the program to be materially false in respect to any item required to be contained therein pursuant to paragraph (a) of this section.

(d) Falsification prohibited. No person may knowingly make, sign, or furnish to a program any consent form which is materially false with respect to any item required to be contained herein pursuant to paragraph (a) of this section.

* * *

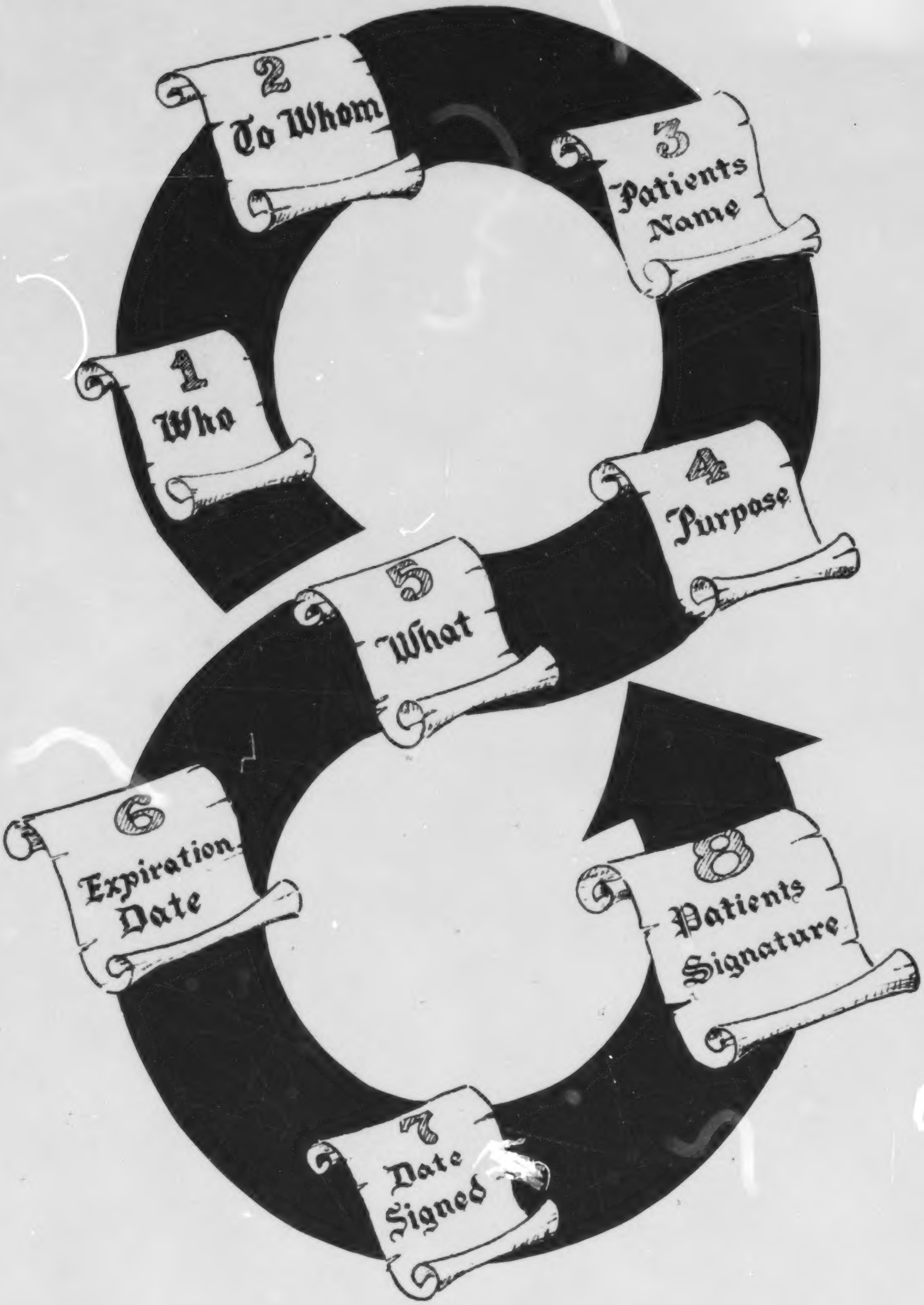
DISCUSSION

The basic legal requirement for a valid consent for the release of information of an alcohol and drug abuse patient's records are detailed in Rule 2.31. The regulations require that a valid consent form include eight specific points:

1. The name of the program which is to make the disclosure
2. The name or title of the person or organization to which disclosure is to be made
3. The patient's name
4. The basic purpose or need for disclosure of the information
5. The extent or nature and kind of information to be disclosed
6. A statement that the consent is subject to revocation at any time except to the extent that action has been taken in reliance thereon, and a specification of the exact date, an event, or the exact condition upon which the consent will expire without express revocation
7. The date when consent is signed by the patient, and
8. The signature of the patient and, when required under Rule 2.15, the signature of a person authorized to give consent under that rule; or when such signature is required under Rule 2.16, the signature of an authorized person is permissible in lieu of the patient.

The reader is advised to follow these Federal requirements. A program or individual is not required to design a form in the numerical order given in

Chart V
Eight Requirements for Valid Consent Form (Rule 2.31)



Rule 2.31; however, any release of information form should conclude with item 7, the date, and item 8, the signature of the patient, or authorized individual in lieu of the patient, in that order.

Programs are advised that there is no 30-day or 60-day duration of consent for the release of information. Any duration of consent is related to the expiration of the purpose or the date specified, the occurrence of an event, or condition of said release.

Programs should check each release of information form to ensure that all comply with the eight requirements of Rule 2.31. If a program releases information pursuant to a consent form that is missing any one or more of these eight requirements, such release violates the Federal regulations and exposes the program to potential liabilities under the regulations. It is essential that requests from other programs and individuals pursuant to a signed release form be checked carefully and, if any of the eight points is missing, this deficient consent form should be returned to the individual or program with a statement noting the exact areas of deficiency. At this point, it might be better to forward your own consent form.

Finally, if any staff person or program has knowledge that information contained in a consent form is false, the consent form should not be honored and no information should be released. Conversely, Rule 2.31(d) of the Federal regulations prohibits any individual from knowingly making, signing, or furnishing to a program any consent form which is materially false with respect to any item. This prohibition applies even to clients who sign consent forms which contain false information.

Points to Remember

- It is important to make sure that all eight requirements are fulfilled before any information is released. No additional requirements and information may be substituted for any of the eight requirements.
- The Federal regulations do not require a signature witness to the consent form. This additional item often appears on consent forms, and programs may or may not include it.
- The Federal regulations do not specify any particular period of consent such as 30 or 60 days. The period of consent should end when the purpose has been fulfilled.
- The client should be advised that he or she may revoke his or her consent prior to the release of the information pursuant to a valid consent form.
- Programs should pay special attention to the signature verification of the patient signing the consent form where the patient is enrolled in his or her own program.
- Programs occasionally include the prohibition against redisclosure as in Rule 2.32 in the consent form. This practice may be continued, or such prohibition against redisclosure may accompany the information released to the party designated in the consent form.

- A sample valid consent form with the eight requirements of the Federal regulations is provided in this manual.

§2.32: PROHIBITION ON REDISCLOSURE

RULE

(a) Notice to accompany disclosure. Whenever a written disclosure is made under authority of this subpart, except a disclosure to a program or other person whose records pertaining to the patient are otherwise subject to this part, the disclosure shall be accompanied by a written statement substantially as follows: "This information has been disclosed to you from records whose confidentiality is protected by Federal law. Federal regulations (42 C.F.R. Part 2) prohibit you from making any further disclosure of it without the specific written consent of the person to whom it pertains, or as otherwise permitted by such regulations. A general authorization for the release of medical or other information is NOT sufficient for this purpose." An oral disclosure may be accompanied or followed by such a notice.

(b) Consent required for redisclosure. A person who receives information from patient records and has been notified substantially in accordance with paragraph (a) of this section is prohibited from making any disclosure of such information except with the specific written consent of the person to whom it pertains, or as otherwise permitted under this part.

(c) Restriction on redisclosure. Whenever information from patient records is needed by any person, such information must be obtained directly from the program maintaining such records and not from another person to whom disclosure thereof has been made, except where the initial disclosure was intentionally and expressly made for the purpose of redisclosure (as for example in the case of an employment agency), or the information is no longer available from the program and redisclosure is not prohibited by any other provision of this part.

* * *

DISCUSSION

Any written disclosure under Subpart C should be accompanied by a written statement that indicates the prohibition on redisclosure stated in Rule 2.32(a) Notice to Accompany Disclosure.

Therefore, persons who receive information from a patient's records and have been notified in accordance with Rule 2.32(a) are prohibited from redisclosing this information except with the required prior written consent of the patient.

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Furthermore, whenever there is a need for information on a patient, the person seeking the information must secure it directly from the program and/or patient with prior written consent of the patient. The only exception to this rule regarding prohibition on redisclosure is where the information has been released with the expressed purpose of redisclosure, as in the case of an employment agency or, as in Rule 2.32(c), the information is no longer available from the program and redisclosure is not prohibited by any other provisions of this part.

Points to Remember

- In the usual case, a written notice prohibiting redisclosure must accompany every written disclosure of information from a patient's record.
- Redisclosure of legally disclosed patient information is prohibited except with the specific consent of the person to whom the information pertains or as otherwise permitted under the regulations.
- The prohibition against redisclosure applies irrespective of whether the person seeking disclosure already has the information, enjoys official status, has obtained a subpoena, or asserts any other justification or basis for the disclosure.
- Individuals and programs making disclosures of patient-identifying information pursuant to Rule 2.32 are advised to develop a statement that can be attached to each release. A rubber stamp with the necessary information may be secured to make any written disclosures. A recommended format is as follows:

> This information has been disclosed to you from records whose confidentiality is protected by Federal law. Federal regulations (42 C.F.R. Part 2) prohibit you from making any further disclosure of it without the specific written consent of the person to whom it pertains, or as otherwise permitted by such regulations. A general authorization for the release of medical or other information, is NOT sufficient for this purpose (see Rule 2.32(a)).

Exercise IV: Development of a Consent Form for Release of Confidential Information, Rule 2.31

Problem

A student was suspended from all classes pending treatment for an apparent drug problem. He enrolled in the drug treatment program.

The student completed the necessary treatment, and sought readmittance to high school. The principal requested a report on his treatment and progress in the program. As a condition, he signed a release form and requested that the drug treatment program forward the necessary information to the principal.

Develop a consent form and appropriate procedures for responding to this request.

Products

1. Individually developed consent form for release of confidential information.
2. Group-developed consent form for release of confidential information.

Directions

1. Meet in your assigned small group. Choose a timekeeper, recorder, and spokesperson.

   Timekeeper: This task is divided into individual and group work. Allow approximately 10 minutes for the individual work, 5 minutes for the exchange of work, and 10 minutes for the group development of the consent form: a total of 25 minutes.

   Recorder: When the group develops its jointly prepared consent form, print the form clearly on newsprint.

   Spokesperson: Be prepared to present/clarify the group's work. Bring newsprint to the main meeting room; display. You will have approximately 5 minutes to present.

2. Individually (without discussing or sharing your work with any other group member) write up a sample release of information form by which information may be released to the principal of the high school. Be sure that the release conforms to the eight points that are required in a valid consent form. Use the blank sheet provided following these instructions to design your form. (This should require no more than 10 minutes.)

3. Upon completion of the individually developed consent form, each participant should exchange this form with the

person sitting next to him or her and critique one another's forms. (Take no more than 5 minutes for this task.)

4. Now, working as a total group, prepare one consent form that draws upon individual members' work and includes all the required items. Put this form on newsprint. (Use about 10 minutes for this task.)

Trainees are urged to seek help, if needed, from the training staff.

SAMPLE

Consent for the Release of Confidential Information

I, ______________________________ of ____________________________________
Name of patient/participant Patient's address

authorize ____ to disclose

to ____ the fol-
Name of person or organization to which disclosure is to be made

lowing information ____________________________________ for the fol-
Extent or nature of information to be disclosed

lowing reason(s) ____
Purpose of need for disclosure

I understand that my records are protected under the Federal and specific State confidentiality laws and regulations and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it (e.g., the provision of treatment upon consent to disclosure to third-party payers) and that in any event this consent expires automatically as described below.

Specification of the date, event, or condition upon which this consent expires

____

____

I further acknowledge that the information to be released was fully explained to me and this consent is given of my own free will.

Executed this day of 19__.

____
Signature of patient

____
Signature of parent or guardian (where required) (Rules 2.15 and 2.16)

____
Signature of person authorized to sign in lieu of patient (where required) (Rules 2.15 and 2.16)

____
Signature of attorney (where required)

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Session 7

Rules 2.33-2.40

7

Session 7
Rules 2.33-2.40

§2.33	Diagnosis, Treatment, and Rehabilitation
§2.34	Prevention of Certain Multiple Enrollments
§2.35	Legal Counsel for Patient
§2.36	Patient's Family and Others
§2.37	Third-Party Payers and Funding Sources
§2.38	Employers and Employment Agencies
§2.39	Criminal Justice System Referrals
§2.40	Situations Not Otherwise Provided For

Learning Objectives

At the end of this session, participants should be able to:

- Comprehend the requirements for releasing information on traveling, incarcerated, or hospitalized patients on medication (Rule 2.33).
- Understand the exception to releasing information without prior written consent as it pertains to disclosure among treatment personnel (Rule 2.33).
- Develop guidelines and a system for an operational central registry (Rule 2.34).
- Design a consent form that meets the requirements for releasing information to an attorney representing a patient in the program (Rule 2.35).
- Establish guidelines for releasing information to parents, spouses, and others (Rule 2.36).
- Develop appropriate systems for dealing with third-party payers (Rule 2.37).
- Draft guidelines for providing confidential information to potential employers and employment agencies interested in hiring patients in the program (Rule 2.38).
- Develop the required forms and procedures for accepting and treating patients who are referred by the various entities of the criminal justice system (Rule 2.39).
- Devise guidelines and procedures for handling situations not provided for in Subpart C (Rule 2.40).

§2.33: DIAGNOSIS, TREATMENT, AND REHABILITATION

RULE

(a) Disclosure authorized. Where consent is given in accordance with §2.31, disclosure of information subject to this part may be made to medical personnel or to treatment or rehabilitation programs where such disclosure is needed in order to better enable them to furnish services to the patient to whom the information pertains.

(b) Traveling, incarcerated, or hospitalized patients on medication. Where a patient on medication is at a distance from his normal residence or treatment program or is incarcerated or hospitalized, or is otherwise unable to deliver a written consent to his treatment program at the time the disclosure is needed, confirmation of the patient's status and information necessary to appropriately continue or modify his medication may be given to medical personnel in a position to provide services to the patient upon the oral representation of such personnel that the patient has requested medication and consented to such disclosure. Any program making a disclosure in accordance with this paragraph shall make a written memorandum showing the name of the patient, or the patient's case number assigned by the program, the date and time the disclosure was made, the information disclosed, and the names of the individuals by whom and to whom it was made.

* * *

DISCUSSION

If a patient on medication is away from his treatment program, is incarcerated, or otherwise unable to deliver a written consent for disclosure when it is needed, the program may give attending medical personnel information necessary to continue or modify his or her medication. However, the medical personnel must state that the patient has requested medication and consented to the disclosure. Any program that makes a disclosure in accordance with this paragraph must make a written memorandum showing:

- Patient's name (or the case number assigned by the program)
- Date and time the disclosure was made
- Information disclosed
- Name of the person disclosing the information
- Name of the person to whom it was disclosed.

Points to Remember

- When a patient receiving medication is away from his or her usual treatment program and needs medication, the treatment program may give the necessary information to medical personnel so that they may provide assistance to the patient.
- The patient's oral consent must be given to personnel requesting disclosure.
- When such disclosure occurs, a memo including the five points listed above must be written.

§2.34: PREVENTION OF CERTAIN MULTIPLE ENROLLMENTS

RULE

(a) Definitions. For the purposes of this section and §2.55--

(1) The terms "administer", "controlled substance", "dispense", "maintenance treatment", and "detoxification treatment" shall respectively have the meanings defined in paragraphs (2), (6), (10), (27), and (28) of section 102 of the Controlled Substances Act (21 U.S.C. 802).

(2) The term "program" means a program which offers maintenance treatment or detoxification treatment.

(3) The term "permissible central registry" means a qualified service organization which collects or accepts, from two or more programs (referred to hereinafter as member programs) all of which are located either within a given State or not more than 125 miles from the nearest point on the border of such State, patient identifying information about persons applying for maintenance treatment or detoxification treatment for the purpose of enabling the member programs to prevent any individual from being concurrently enrolled in more than one such program.

(b) Use of central registries prohibited except as expressly authorized. The furnishing of patient identifying information by a program to any central registry which fails to meet the definition of a permissible central registry set forth in paragraph (a)(3) of this section is prohibited, and the furnishing of patient identifying information to or by any central registry except as authorized in this section is prohibited. Information pertaining to patients held by a central registry may be furnished or used in accordance with paragraphs (e), (f), and (g) for the purpose of preventing multiple enrollments, but may not be otherwise furnished or used in connection with any legal, administrative, supervisory, or other action with respect to any patient.

(c) Safeguards and procedures required. To minimize the likelihood of disclosures of information to impostors or others seeking to bring about unauthorized or improper disclosure, any communications carried on by programs pursuant to this section must be conducted (1) by authorized personnel designated in accordance with §2.17(b), and (2) in conformity with procedures established in accordance with that section.

(d) Disclosures with respect to patients in treatment. A member program may supply patient identifying information and information concerning the type of drug used or to be used in treatment and the dosage thereof, with relevant dates, to a permissible central registry with respect to any patient--

(1) When the patient is accepted for treatment,

(2) When the type or dosage of the drug is changed, and

(3) When the treatment is interrupted, resumed, or terminated.

(e) Disclosures with respect to applications. When any person applies to a program for maintenance treatment or detoxification treatment, then for the purpose of inquiring whether such person is currently enrolled in another program for such treatment, the program may furnish patient identifying information with respect to such person--

(1) To any permissible central registry of which the program is a member, and

(2) To any other program which is not more than 200 miles distant and which is not a member of any central registry of which the inquiring program is a member.

(f) Program procedure in case of apparent concurrent enrollment. When an inquiry pursuant to paragraph (e)(2) is made of another treatment program and its response is affirmative, the two programs may engage in such further communication as may be necessary to establish whether an error has been made, and if none, the programs should proceed in accordance with sound clinical practice and any applicable regulations pertaining to the type of treatment involved.

(g) Registry procedure in case of apparent concurrent enrollment. When an inquiry pursuant to paragraph (e)(1) is made of a permissible central registry and its response is affirmative, it may advise the inquiring program of the name, address, and telephone number of the other program, or it may advise the other program of the identity of the patient and the name, address, and telephone number of the inquiring program, or it may do both, and in any case the two programs may then communicate as provided in paragraph (f) above.

(h) Advice to patients. When the policies and procedures of any program involve any disclosures pursuant to this section, before any patient is accepted for or continued in treatment (other than detoxification treatment) after September 30, 1975, written consent in accordance with § 2.31 shall be obtained. Such consent shall set forth a current list of the names and addresses either of any programs or of any central registries to which such disclosures will be made. Notwithstanding the requirement of §2.31 (a)(2), such consent shall be effective with respect to any other such program thereafter established within 200 miles, or any registry serving such programs, and shall so state. Such consent shall be effective for as long as the patient remains enrolled in the program to which it is given.

* * *

DISCUSSION

After September 30, 1975, if a program wishes to disclose information to a central registry or to other programs under this section, the following procedures apply:

- Written consent for the disclosure of information must be obtained from the patient as a condition of acceptance for, or continuance in, the program.
- The consent form must comply with the eight required points.
- The patient must be informed of the current lists of names and addresses of programs or central registries to which disclosures will be made.
- The consent will be valid so long as the patient remains in the program.

Points to Remember

- A treatment program may supply relevant data to the central registry when:
  - A patient is accepted for treatment.
  - Type or dosage of medication is changed.
  - Treatment is interrupted, resumed, or terminated.
- Specific patient-identifying information can be released by a central registry to a nonmember program within a 200-mile radius to determine if a patient is enrolled in more than one program.
- If multiple enrollments are found, the central registry may provide relevant information to the programs involved in order to rectify the situation. Decisions here will be left to the judgment of the programs involved.

§2.35: LEGAL COUNSEL FOR PATIENT

RULE

When a bona fide attorney-client relationship exists between an attorney-at-law and a patient, disclosure of any information in the patient's records may be made to the attorney upon the written application of the patient endorsed by the attorney. Information so disclosed may not be further disclosed by the attorney.

* * *

DISCUSSION

A patient in a treatment program may request a program to disclose information to an attorney who represents him or her.

The program must request that the patient fill out a Rule 2.31 consent form and take it to the attorney for said form to be endorsed by the attorney.

The program releasing the information to the attorney should include the Rule 2.32 prohibition against further disclosure. The purpose of this prohibition is to guard against the possibility that the attorney might be forced to serve as a conduit for otherwise prohibited disclosure to any third parties. Normally, the attorney-client privilege is sufficient to limit disclosure. This privilege is subject to waiver by the client. The Rule 2.35 prohibition against further disclosure cannot be waived by the client.

Points to Remember

- The program cannot disclose information to an attorney unless it has verified that an attorney-client relationship exists. This verification is established by requiring the client to complete a Rule 2.31 written consent form which must be signed by the client and the attorney prior to the release of any information by the program.
- The program must refuse disclosure of the requested information if the procedures are not followed.
- A copy of Rule 2.35 should accompany the disclosure to give further notice to the attorney of the need to comply with 42 C.F.R., Part 2.
- The program is advised to include the procedures for releasing information as part of its patient education activities.

§ 2.36: PATIENT'S FAMILY AND OTHERS

RULE

Where consent is given in accordance with §2.31, information evaluating his current or past status in a treatment program may be furnished to any person with whom the patient has a personal relationship unless, in the judgment of the person responsible for the patient's treatment, the disclosure of such information would be harmful to the patient.

* * *

DISCUSSION

Information that includes an evaluation of the patient's current or past status in the treatment program may be disclosed to any person with whom the person has a personal relationship, as long as the consent has been given in accordance with the eight required items covered under Rule 2.31. However, this does not apply when there is reason to believe that disclosure of such information would be damaging to the patient.

Points to Remember

When disclosure is made to a patient's family:

- Where the program is an inpatient or residential program, it is suggested that at intake the program secure written consent from the patient to release information regarding his or her status to the spouse, family, visitors, or others.
- Disclosure is not authorized if, in the determination of the program, disclosure would be damaging to the patient.

Chart VI
Patient's Family and Others (Rule 2.36)

"HELLO. . . I'M AN OLD FRIEND OF MISS HOOD. IS SHE IN YOUR PROGRAM?"

Information on a patient's status in the program may be disclosed to any person with whom the patient has a personal relationship as long as consent has been given in accordance with the eight required items, except when the person in charge believes such a disclosure would hurt the patient.

§2.37: THIRD-PARTY PAYERS AND FUNDING SOURCES

RULE

(a) Acquisition of information. Disclosure of patient information to third party payers or funding sources may be made only with the written consent of the patient given in accordance with §2.31 and any such disclosure must be limited to that information which is reasonably necessary for the discharge of the legal or contractual obligations of the third party payer or funding source.

(b) Prohibition on disclosure. Where a funding source or third party payer maintains records of the identity of recipients of treatment or rehabilitation services for alcohol or drug abuse such records are, under the authorizing legislation, maintained in connection with the performance of an alcohol or drug abuse prevention function and are subject to the restrictions upon disclosure set forth in this part.

* * *

DISCUSSION

Rule 2.37 requires that the confidentiality of the client be protected by the program by securing the prior written consent of the client before the program shares with or submits any patient information for verification and payment by a third-party payer. It is appropriate and necessary that prior written consent be obtained from the patient during the intake process.

The third-party payer or funding source may request any necessary patient information pursuant to a valid consent to verify and process the patient's claims. The patient's records and information stored by the third-party payer and funding source must be maintained in a secure and confidential manner in accordance with Rule 2.17 dealing with the security of records. Any information so obtained on an alcohol and drug abuse patient cannot be redisclosed without the prior written consent of the patient whose records are involved except as authorized by the regulations.

Prohibition on Disclosure

The third-party payer or funding source may keep records on the identity of participants in an alcohol or drug abuse program, but these records are protected by the Federal regulations, and the information cannot be disclosed except as authorized by the regulations (Rule 2.37).

Points to Remember

For disclosure of information to third-party payers and funding sources:

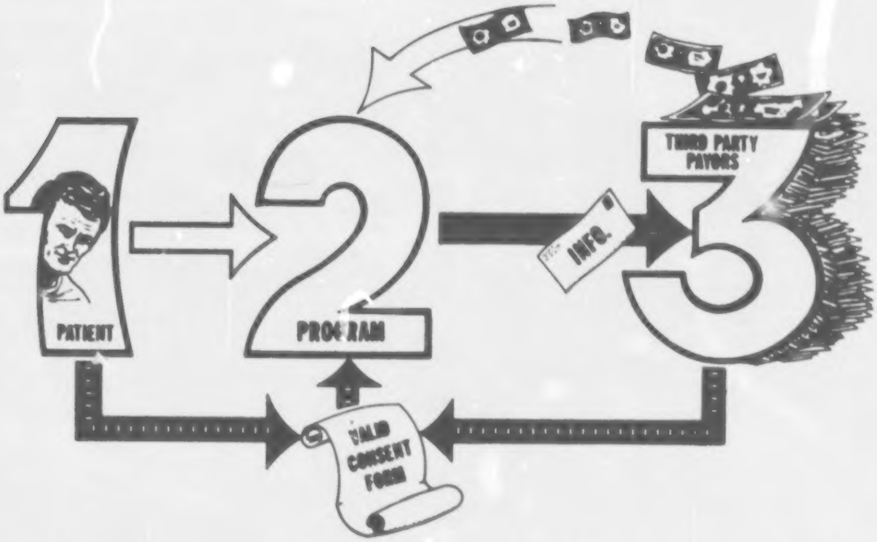
- Written consent must comply with the eight points required under Rule 2.31.

- Information disclosed must be confined to that which is needed to fulfill the contractual obligation of the third-party payer or funding source.

- Information disclosed to the third-party payer cannot be redisclosed without the written consent of the patient.

- Any information disclosed to a third-party payer must be accompanied by the statement on prohibition against redisclosure in Rule 2.32(a). The billing staff should be aware of these requirements in the Federal regulations.

Chart VII
Third-Party Payers (Rule 2.37)



- Programs must inform patients of their eligibility to receive payment for the services of the program. However, these payments will be secured by the program as reimbursement for services rendered to the client.
- A valid consent form in accordance with Rule 2.31 must be secured from the patient before the program can communicate information about the patient and/or bill the third-party payer for services.
- Once the program has secured a valid written consent form from the patient, the program can send bills and information to the third-party payer requesting reimbursement for all services provided to the patient.

§2.38: EMPLOYERS AND EMPLOYMENT AGENCIES

RULE

(a) Disclosure permitted. Where consent is given in accordance with §2.31, a program may make disclosures in accordance with this section.

(b) Eligible recipients. A program may make disclosure under this section to public or private employment agencies, employment services, or employers.

(c) Scope of disclosure. Ordinarily, disclosures pursuant to this section should be limited to a verification of the patient's status in treatment or a general evaluation of progress in treatment. More specific information may be furnished where there is a bona fide need for such information to evaluate hazards which the employment may pose to the patient or others, or where such information is otherwise directly relevant to the employment situation.

(d) Criteria for approval. A disclosure under this section may be made if, in the judgment of the program director or his authorized representative appointed as provided in §2.17(b), the following criteria are met:

(1) The program has reason to believe, on the basis of past experience or other credible information (which may in appropriate cases consist of a written statement by the employer), that such information will be used for the purpose of assisting in the rehabilitation of the patient and not for the purpose of identifying the individual as a patient in order to deny him employment or advancement because of his history of drug or alcohol abuse.

(2) The information sought appears to be reasonably necessary in view of the type of employment involved.

* * *

DISCUSSION

Rule 2.38 of the Federal regulations permits a program to disclose information on alcohol and drug abuse patients to employers and employment agencies providing that consent of the patient is acquired in accordance with Rule 2.3l. The program is advised to limit such disclosure to a verification of the patient's status in the treatment and general progress (Rule 2.38(c)). Any additional information released will depend on the nature and type of employment and the need for the information in light of any unusual hazards that might impact on the patient in the work environment.

This section of the regulations also permits a client, in accordance with Rule 2.3l, to give an employment agency the right to redisclose information to potential employers without violating Rule 2.31 or Rule 2.32 on prohibition of redisclosure.

Points to Remember

- Written consent is required before information can be given to employers, employment agencies, and employment services.

- Disclosure may be made in accordance with the valid consent of the patient only if the information:

    - Contributes to the patient's rehabilitation and is reasonably necessary in view of the type of employment involved, and

    - Is not used as a basis of firing, refusing to hire, or denying advancement.

- It should be noted that an exception is made to the prohibition against redisclosure (Rule 2.32) in the case of information released (in accordance with the consent form in Rule 2.31) to an employment agency, employment service, or employment agent, because consent is presumed to include authorization for redisclosure. However, the authorization pursuant to a valid consent form in Rule 2.31 should explicitly state that the client gives written consent for redisclosure by the employment agency or service.

- Programs must ensure that consent given pursuant to Rule 2.38, for the purpose of securing employment, should be informed consent where the client/patient acts knowingly, willingly, intelligently, without duress, and with full understanding of the positive and negative effects of disclosing such information to an employer and/or employment agency.

§2.39: CRIMINAL JUSTICE SYSTEM REFERRALS

RULE

(a) Consent authorized. Where participation by an individual in a treatment program is made a condition of such individual's release from confinement, the disposition or status of any criminal proceedings against him or the execution or suspension of any sentence imposed upon him, such individual may consent to unrestricted communication between any program in which he is enrolled in fulfillment of such condition and (1) the court granting probation, or other post-trial or pretrial conditional release, (2) the parole board or other authority granting parole, or (3) probation or parole officers responsible for his supervision.

(b) Duration of consent. Where consent is given for disclosures described in paragraph (a) of this section, such consent shall

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expire sixty days after it is given or when there is a substantial change in such person's status, whichever is later. For the purposes of this section, a substantial change occurs in the status of a person who, at the time such consent is given, has been--

(1) Arrested, when such person is formally charged or unconditionally released from arrest;

(2) Formally charged, when the charges have been dismissed with prejudice, or the trial of such person has been commenced;

(3) Brought to a trial which has commenced, when such person has been acquitted or sentenced;

(4) Sentenced, when the sentence has been fully executed.

(c) Revocation of consent. An individual whose release from confinement, probation, or parole is conditioned upon his participation in a treatment program may not revoke a consent given by him in accordance with paragraph (a) of this section until there has been a formal and effective termination or revocation of such release from confinement, probation, or parole.

(d) Restrictions on redisclosure. Any information directly or indirectly received pursuant to this section may be used by the recipients thereof only in connection with their offical duties with respect to the particular individual with respect to whom it was acquired. Such recipients may not make such information available for general investigative purposes, or otherwise use it in unrelated proceedings or make it available for unrelated purposes.

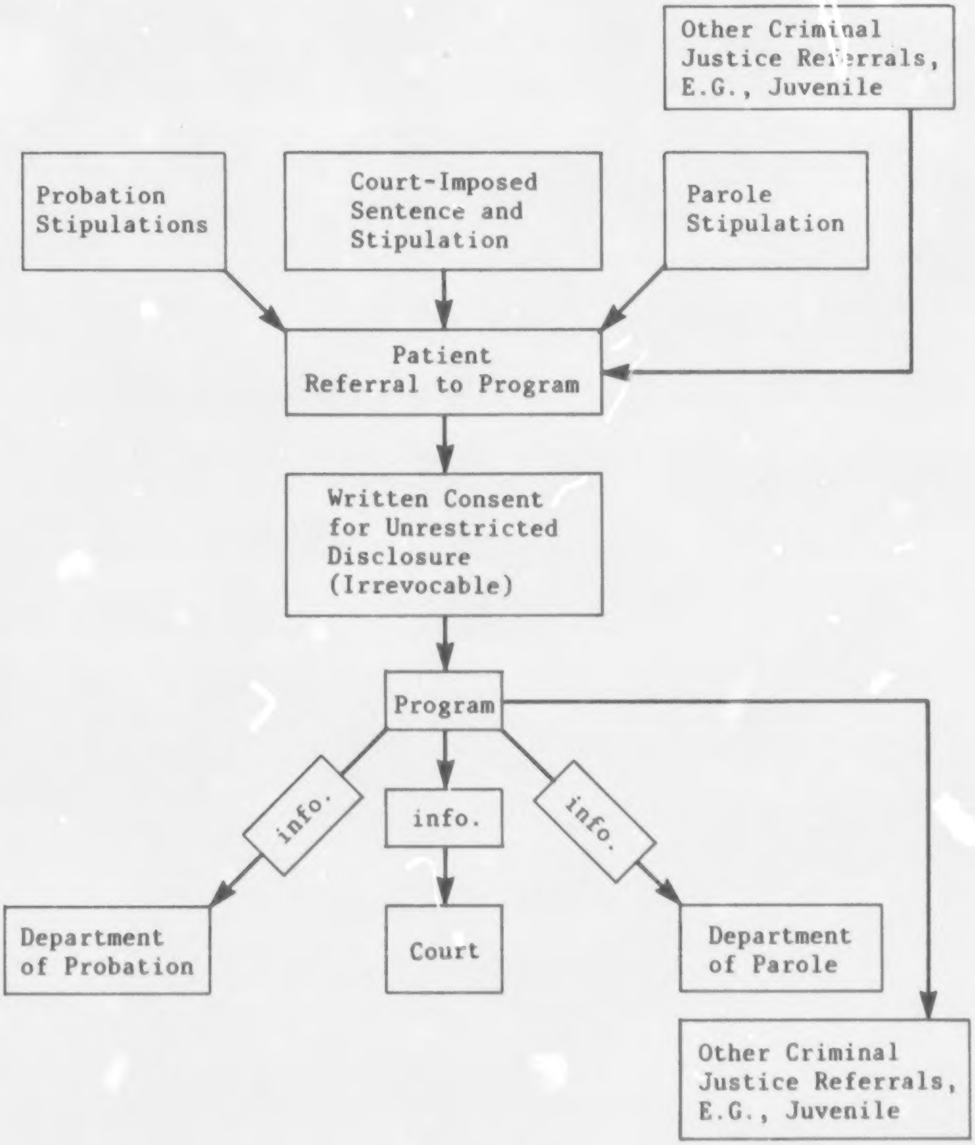
* * *

DISCUSSION

Rule 2.39 provides a basis for establishing good working relationships between the criminal justice system and treatment programs. This relationship is necessary in light of the large number of clients who are referred from the criminal justice system to alcohol and drug abuse programs. In some instances more than 50 percent of the client load is made up of criminal justice referees.

This rule 2.39 covers a patient referred to alcohol and drug abuse programs as a condition of release from confinement or the disposition or status of any criminal proceedings against him or her or the execution or suspension of any sentence imposed upon him or her (Rule 2.39(a)). Such individuals may consent to unrestricted communication between the treatment program and the court granting probation, or other post- or pre-trial conditional release by the court, the parole board, or other probation or parole officers responsible for his or her supervision. However, the client, program, parole officer,

Chart VIII
Criminal Justice Referrals (Rule 2.39)


Other Criminal Justice Referrals, E.G., Juvenile
Probation Stipulations
Court-Imposed Sentence and Stipulation
Parole Stipulation
Patient Referral to Program
Written Consent for Unrestricted Disclosure (Irrevocable)
Program
info.
info.
info.
Department of Probation
Court
Department of Parole
Other Criminal Justice Referrals, E.G., Juvenile

NOTE:

The client's written consent is required when there is a criminal justice referral, in order to share unrestricted information with any entity of the criminal justice system. Any revocation of the client's written consent may be prohibited by Rule 2.39(c).

probation officer, or court may agree to release only pursuant to a valid consent form as in Rule 2.31.

The program must recognize the skills of the probation and parole officer for, in many instances, they need to have the information so that they can intervene at an early stage. In some cases, this intervention will make a difference between the failure or the success of a patient who is referred by the criminal justice system. Nothing in the Federal regulations and Rule 2.39 prohibits alcohol and drug programs from entering into agreements and arrangements with criminal justice agencies to regulate or restrict the subject matter or form of communication and sharing of information about patients. For example, a program might agree pursuant to a valid consent form from the patient (Rule 2.31) to oral communication about specific matters, while restricting formal written reports by the program to objective data such as attendance, urinalysis, progress, and termination.

Finally, any information that is released by a program to parole or probation officers is subject to a prohibition against redisclosure for general investigative purposes or for unrelated proceedings. The information should be used only in connection with the official purposes in connection with the parole, probation, and court responsibilities relative to this client.

Points to Remember

- If an individual's participation in an alcohol or drug abuse treatment program is a condition of release from confinement or disposition of criminal proceedings or sentencing, the individual may provide valid consent for unrestricted disclosure to:
    - A court granting probation or other conditional release
    - A parole board
    - The probation or parole officer responsible for the individual's supervision.
- Information disclosed under this section cannot be redisclosed by the recipients thereof other than in connection with their official duties related to individual treatment or supervision of the client.

Example

Probation officers who receive information from a treatment program cannot enter that information as evidence in a grand jury investigation unrelated to the purpose for which the consent was given under this rule.

§2.40: SITUATIONS NOT OTHERWISE PROVIDED FOR

RULE

(a) Criteria for approval. In any situation not otherwise specifically provided for in this subpart, where consent is given in accordance with §2.31, a program may make a disclosure for the benefit of a patient from the records of that patient if, in the judgment of the program director or his authorized representative appointed as provided in §2.17, all of the following criteria are met:

(1) There is no suggestion in the written consent or the circumstances surrounding it, as known to the program, that the consent was not given freely, voluntarily, and without coercion.

(2) Granting the request for disclosure will not cause substantial harm to the relationship between the patient and the program or to the program's capacity to provide services in general.

(3) Granting the request for disclosure will not be harmful to the patient.

(b) Circumstances deemed beneficial. For the purposes of this section, the circumstances under which disclosure may be deemed to be beneficial to a patient include, but are not limited to, those in which the disclosure may assist the patient in connection with any public or private claim, right, privilege, gratuity, grant or other interest accruing to, or for the benefit of, the patient or the patient's immediate family. Examples of the foregoing include welfare, medicare, unemployment, workmen's compensation, accident or medical insurance, public or private pension or other retirement benefits, and any claim or defense asserted or which is an issue in any civil, criminal, administrative or other proceeding in which the patient is a party or is affected.

* * *

DISCUSSION

Rule 2.40 allows the program to disclose patient-identifying information to a third party (with prior written consent in accordance with Rule 2.31), in order to secure a benefit that the client is entitled to or where there is a claim, privilege, gravity, grant, or other interest accruing to and for the benefit of the client.

This section of the Federal regulations allows a program to act in almost any area where such action will benefit the patient.

It is advisable that consent so acquired should be informed consent and the client be given full disclosure about positive and negative aspects. Such consent should be made so that the patient can act knowingly, willingly, intelligently, and without coercion.

Points to Remember

In order to disclose information from a patient's record under Rule 2.40, the following criteria must be met:

- The patient must have provided prior written consent in accordance with Rule 2.31.
- A determination must be made by the program director or representative authorized by the director.
- The consent of the patient, when given, must be informed consent and had been given without any coercion or fear of reprisal.
- The information disclosed from the patient's record cannot harm either the patient or the program.
- The disclosure of this information will benefit the patient.

Exercise V: The Central Registry, Rule 2.34 (Optional)

Problem

John Smith, Assistant Administrator of the Lake Regional Methadone Maintenance Program, calls the central registry of the Lakes Program. He inquires about a client's possible enrollment in any other program, the type of dosage received, and "any other information."

Products

1. On Flipchart A: "Yes" or "No" decisions and justification for your answers to the following questions:

   Question 1: "Is a central registry permissible under these circumstances?"

   Question 2: "Could the central registry respond to the request of the Lake Program without violating any confidentiality laws?"

2. On Flipchart B: A list providing information about such a central registry as it should be provided to clients at the time of their enrollment.

Directions

1. Meet in your assigned small group. Choose a timekeeper, recorder, and spokesperson.

   Timekeeper: The entire task is to be completed within 20 minutes. Help the group finish on schedule.

   Recorder: Label two flipcharts "A" and "B." Organize the group's responses to the two products required and print on flipcharts.

   Spokesperson: Be prepared to present/clarify the group's work. Bring flipcharts to main meeting room; display. You will have about 4-5 minutes to present.

2. Working as a group, answer the question, "Is a central registry permissible under these circumstances?" Briefly justify (explain) your answer. Put on top half of Flipchart A.

3. Now answer the question, "Could the central registry respond to the request of the Lake Regional Methadone Maintenance Program without violating any confidentiality?" Put your conclusion and brief justification on the bottom half of Flipchart A.

4. As a group, develop a list of items that responds to the question, "What information about such a central registry should be provided to clients at the time of enrollment?" Place this list on Flipchart B.

Trainees are urged to seek help, if needed, from the training staff.

Exercise VI: Criminal Justice System Referrals, Rule 2.39

Problem

Mr. Arthur Millhouse has received parole from the State Correctional Center with the stipulation that he enroll immediately in a drug treatment program. In compliance with this stipulation, Mr. Millhouse has provided his written consent authorizing the release of all information pertaining to his enrollment, attendance, lab results, and treatment plan.

At the end of the specified period of parole, Mr. Millhouse's parole officer requests information from the program that he feels might be helpful in lining up a prospective job for Mr. Millhouse.

Products

1. Individually developed outline of procedures for handling this matter.
2. Group-developed composite outline of procedures for handling this matter.

Directions

1. Meet in your assigned small group. Choose a timekeeper, recorder, and spokesperson.

   Timekeeper: This task is divided into individual and group work. Allow approximately 5 minutes for the individual work, 5 minutes for the exchange of work, and 5 minutes for the group development of the procedural outline, for a total of 15 minutes.

   Recorder: When the group develops its composite outline, print the procedures clearly on newsprint.

   Spokesperson: Be prepared to present/clarify the group's work. Bring newsprint to the main meeting room, display. You will have approximately 5 minutes to present.

2. Working individually (without discussing or sharing your work with any other group member) outline what you would deem appropriate procedures in handling this matter. Be specific. (5 minutes)
3. Exchange your outline with another person within your group. Give one another feedback and determine if the outline you now have reflects a usable set of procedures. (5 minutes)

4. Working as a small group, draw up one composite outline representing a set of procedures that would provide a responsible structure for handling this matter. Put this outline on newsprint.

Trainees are urged to seek help, if needed, from the training staff.

Session 8

Feedback on Exercise III

Session 8
Feedback on Exercise III

In this session, the issues of current and former employees are addressed, and the group will discuss Exercise III.

Session 9

Subpart D
Disclosures Without Patient Consent
Rules 2.51-2.54

Session 9

Subpart D—Disclosures Without Patient Consent—Rules 2.51-2.54

§2.51 Medical Emergencies
§2.52 Research, Audit, and Evaluation
§2.53 Government Agencies
§2.54 Patient Identifying Information in Connection with Examinations

Learning Objectives

At the end of this session, participants should be able to:

- Develop appropriate systems for releasing information when a bona fide emergency exists (Rule 2.51).
- Develop guidelines and procedures for disclosing patient-identifying information to qualified personnel for the purpose of an audit, evaluation, and research (Rule 2.52).
- Understand the circumstances under which governmental agencies may have access to patient-identifying information (Rule 2.53).
- Develop procedures for disclosing information in connection with examinations; in particular, the procedure for disposition of these records by the examiners (Rule 2.54).

§2.51: MEDICAL EMERGENCIES

RULE

(a) In general. Disclosure to medical personnel, either private or governmental, is authorized without the consent of the patient when and to the extent necessary to meet a bona fide medical emergency.

(b) Food and Drug Administration. Where treatment involves the use of any drug, and appropriate officials of the Food and Drug Administration determine that the life or health of patients may be endangered by an error in the manufacture or packaging of such drug, disclosure of the identities of the recipients of the drug may be made without their consent to appropriate officials of the Food and Drug Administration to enable them to notify the patients or their physicians of the problem in order that corrective action may be taken.

(c) Incapacitated persons. Where a patient is incapacitated and information concerning the treatment being given him by a program is necessary to make a sound determination of appropriate emergency treatment, such information may be given without the

patient's consent to personnel providing such emergency treatment.

(d) Notification of family or others. When any individual suffering from a serious medical condition resulting from drug or alcohol abuse is receiving treatment at a facility which is within the scope of this Part the treating physician may, in his discretion, give notification of such condition to a member of the individual's family or any other person with whom the individual is known to have a responsible personal relationship. Such notification may not be made without such individual's consent at any time such individual is capable of rational communication.

(e) Record required. Any program making an oral disclosure under authority of this section shall make a written memorandum showing the patient's name or case number, the date and time the disclosure was made, some indication of the nature of the emergency, the information disclosed, and the names of the individuals by whom and to whom it was disclosed.

* * *

DISCUSSION

Rule 2.51(a) authorizes disclosure without the prior written or oral consent of the patient, to medical personnel (i.e., doctor and nurses), when such disclosure of patient-identifying information is necessary to meet a bona fide medical emergency; i.e., a life-threatening situation.

Rule 2.5l(b) authorizes disclosure of the identities of patients to Food and Drug Administration officials where treatment involves the use of a drug and where the FDA has determined that the life or health of patients might be endangered by an error in manufacturing or packaging of a particular drug. In these circumstances, the program may make such disclosure of patient-identifying information without the prior written consent of the patients so affected.

Rule 2.5l(c) authorizes disclosure of patient-identifying information without the consent of the patient if a patient is incapacitated, which means temporary inability to understand, communicate, or perform a necessary intellectual, emotional, and physical act, or suffering from severe effects of drugs or alcohol. However, such disclosure of the patient's information is limited to when a patient is receiving emergency treatment and the information is necessary to assist the personnel in providing such emergency treatment. It is important to note the difference between an "incompetent patient" under Rule 2.16, someone adjudicated by a court as being incompetent, and an "incapacitated patient," someone adjudged by the treatment personnel to be incapable of making decisions, responding to communication, drunk, under the severe effects of a drug, and so forth.

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Rule 2.5l(d) authorizes a treatment program to make disclosures without the patient's consent when the patient is suffering from a serious medical condition resulting from the use of alcohol or drugs. Disclosure of the patient's condition may at the discretion of the program be made to a family member or any other person with whom the individual is known to have a close personal relationship. The program should verify such a relationship to ensure that the information is being released to an individual authorized by Rule 2.5l(d). An important exception to the release of the patient's records is indicated in 2.5l(d), which prohibits the treatment program from disclosing any patient-identifying information to a family member or person who has a close personal relationship with the patient, if the patient is capable of rational communication notwithstanding the abuse of alcohol or drugs.

Finally, in all instances in which a bona fide medical emergency exists, or if the FDA has determined that a drug is harmful to patients, or a patient is incapacitated, the program making such disclosure to a third party, i.e., medical personnel, should make sure that a written memorandum is completed with all of the requirements stated in Rule 2.5l(e).

Points to Remember

- In medical emergencies where there is a life-threatening condition affecting the client, a program involved in treating alcohol and drug abuse patients may disclose necessary patient-identifying information from the patient's record without consent of the patient to medical personnel.

- An attending physician and other medical personnel and a treatment program may notify a patient's family or a person with whom the patient has a responsible personal relationship, without the patient's consent, if there is a medical emergency and the patient is incapable of rational communication or/and is incapacitated. However, once the patient regains a rational state and can communicate rationally,the patient's consent must be secured before any disclosure of information to a third party is made.

- In making disclosure of any patient records without the patient's consent, a program must write a memorandum containing all seven points stipulated in Rule 2.5l(e). This memorandum should be filed and placed in the patient's permanent records.

- The specific requirements of the memorandum in Rule 2.5l(e) are that it contain:

  1. Patient's name or case number
  2. Date of disclosure
  3. Time the disclosure was made
  4. Nature of the emergency
  5. Information disclosed
  6. Name of the individual by whom disclosure was made
  7. The person(s) to whom disclosure was made.

  Note that Rule 2.5l(e) does not require that the memorandum be witnessed.

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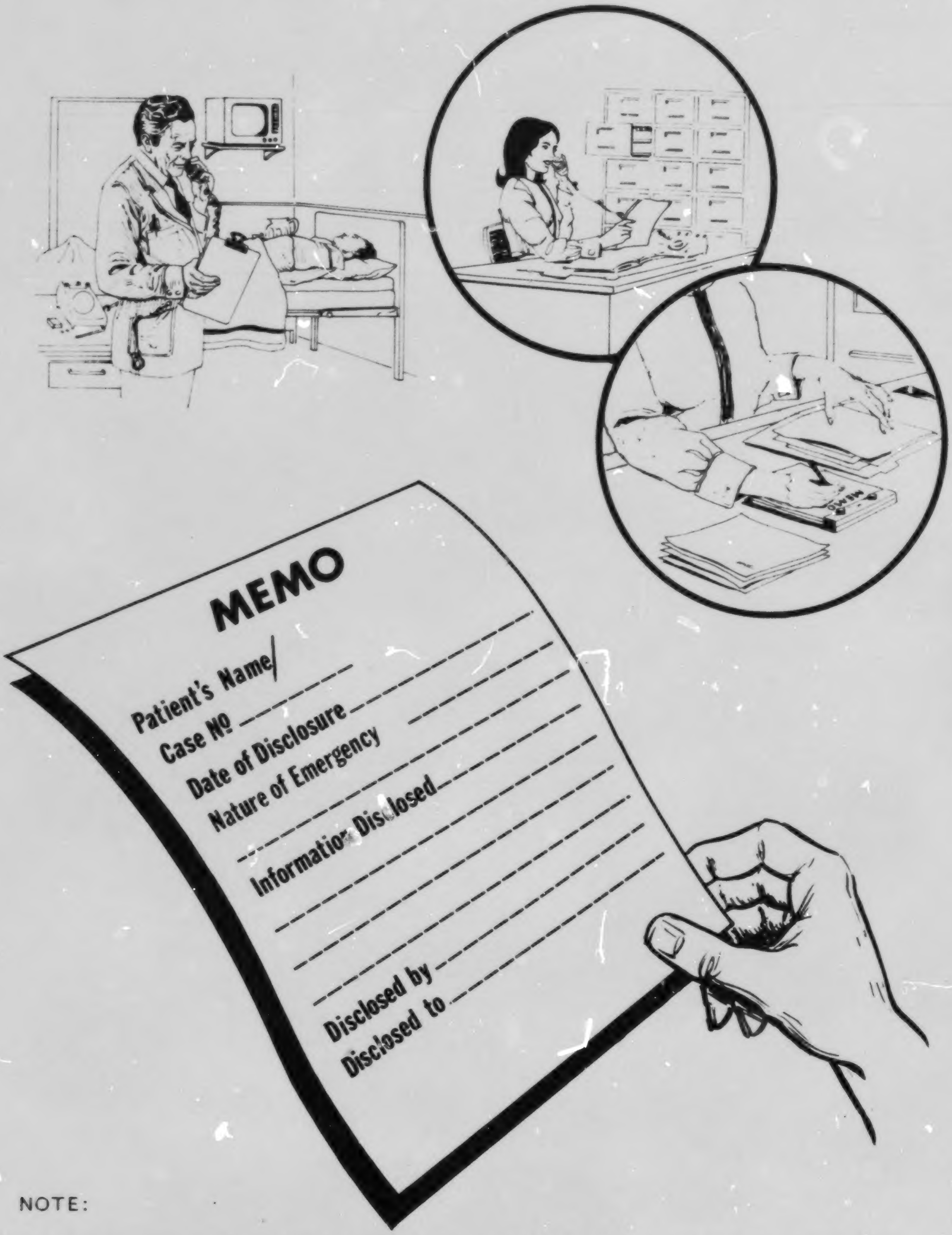
Chart IX
Medical Emergencies and Telephone Releases (Rule 2.51)



MEMO

Patient's Name

Case No

Date of Disclosure

Nature of Emergency

Information Disclosed

Disclosed by

Disclosed to

NOTE:

This sample memo should be used for oral release of information over the phone and in cases of medical emergencies.

§ 2.52: RESEARCH, AUDIT, AND EVALUATION

RULE

(a) Research, audit, and evaluation. Subject to any applicable specific provision set forth hereinafter in this subpart, the content of records pertaining to any patient which are maintained in connection with the performance of a function subject to this part may be disclosed, whether or not the patient gives consent, to qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner. For the purposes of this subpart and for the purposes of subsection (b)(2)(B) of the authorizing legislation, the term "qualified personnel" means persons whose training and experience are appropriate to the nature and level of the work in which they are engaged and who, when working as part of an organization, are performing such work with adequate administrative safeguards against unauthorized disclosures.

(b) Uses of disclosures of patient identifying information.

(1) Where a disclosure made to any person pursuant to paragraph (a) of this section includes patient identifying information with respect to any patient, such information may not be further disclosed, and may not be used in connection with any legal, administrative, supervisory, or other action whatsoever with respect to such patient, except as provided in paragraphs (b)(2) and (b)(3) of this section.

(2) The inclusion of patient identifying information in any written or oral communication between a person to whom a disclosure has been made pursuant to paragraph (a) and the program making such disclosure does not constitute the identification of a patient in a report or otherwise in violation of paragraph (a).

(3) Where a disclosure is made pursuant to paragraph (a) of this section to a person qualified to determine, on the basis of such disclosure, the presence of a substantial risk to the health and well being, whether physical or psychological, of any patient, and, in the judgment of such person, such a risk exists and the situation cannot be dealt with solely by means of communications as described in paragraph (b)(2) of this section without intensifying or prolonging the risk as compared with other means of dealing with it, then the initial disclosure under paragraph (a) and any subsequent disclosure or redisclosure of patient identifying information for the purpose of reducing the risk to the patient involved shall be subject to the provisions of § 2.51.

* * *

DISCUSSION

Rule 2.52 authorizes the disclosure of information about an alcohol or drug abuse patient for purposes of financial, program, and management audit and monitoring, and program evaluation, and also for conducting scientific research without the prior written or oral consent of the patient. However, such qualified personnel are prohibited from disclosing in any report directly or indirectly any patient-identifying information. Very often programs will be required by State and Federal and private funding sources to release or at least provide access to patient-identifying information. Rule 2.52 permits disclosure of patient-identifying information to the funding sources or monitoring sources for the limited purposes of management, financial and program audit, and program evaluation or for conducting scientific research.

Points to Remember

- It is important to understand that Rule 2.52 defines "qualified personnel" as those persons whose training and experience are appropriate to the nature and level of the work in which they are engaged, and who, when working as part of an organization, are performing such work with adequate administrative safeguards against unauthorized disclosures. This means that "qualified personnel" should be designated and assigned by State, Federal, and other agencies to conduct the activities referred to in this rule, which includes conducting scientific research, management, program and financial audits, and program evaluation and monitoring of alcohol and drug abuse programs.

- Rule 2.52 prohibits a recipient of patient-identifying information resulting from a financial, program, management audit, program evaluation, or research from redisclosing this information or using it in connection with any legal, administrative, supervisory, or other action with respect to the patient. (Rule 2.52(b)(l).)

- Rule 2.52(b)(2) permits an auditor to include patient identifying information in any oral or written report that is shared directly between the auditor and the program, and this does not constitute a disclosure.

- A very important part of this Rule is 2.52(b)(3), which permits a qualified person who, pursuant to a disclosure during an audit, determines, based on his or her qualifications, that there is the presence or potential of substantial risk to the health and well-being of any patient, whether physical or psychological, to release patient-identifying information and other general or specific information for the purpose of reducing this perceived risk to the patient. It is essential that the qualified person making such disclosure comply with the requirements detailed in Rule 2.5l.

- Rule 2.52 permits each program involved in alcohol and drug abuse activities to develop its own guidelines and procedures for conducting scientific research and evaluation. Again, such activity may be conducted without the prior written or oral consent of the patient(s).

- Rule 2.52 permits each State and Federal entity involved in alcohol and drug abuse activities concerning patients affected by alcohol or drugs to develop its own guidelines and procedures for conducting scientific research and evaluation. Again, such research and evaluation activities may be conducted without prior oral or written consent of the patient(s).

- Prior to conducting any audit and evaluation and scientific research involving qualified personnel other than program staff, the program and such qualified personnel should meet and establish clear guidelines and procedures that will ensure compliance with Rule 2.52 and all of the requirements for protection of the privacy and confidentiality of the patient and that will ensure that the prohibition against redisclosure will be observed.

§2.53: GOVERNMENTAL AGENCIES

RULE

(a) In general. Where research, audit, or evaluation functions are performed by or on behalf of a State or Federal governmental agency, the minimum qualifications of personnel performing such functions may be determined by such agency, subject to the provisions of this part, with particular reference to the organizational requirements and limitations on the categories of records subject to review by different categories of personnel.

(b) Financial and administrative records. Where program records are reviewed by personnel who lack either the responsibility for, or appropriate training and supervision for, conducting scientific research, determining adherence to treatment standards, or evaluating treatment as such, such review should be confined as far as practicable to administrative and financial records. Under no circumstances should such personnel be shown caseworker or counsellor notes, or similar clinical records. Programs should organize their records so that financial and administrative matters can be reviewed without disclosing clinical information and without disclosing patient identifying information except where necessary for audit verification.

(c) Scientific research and long-term evaluation studies. No State and no agency or political subdivision of a State may require, as a condition to funding, licensing, or otherwise, that any program furnish patient identifying information for the purpose of conducting scientific research or long-term evaluation studies unless the recipient of such information is legally required to hold such information in confidence, is prohibited from taking any administrative, investigative, or other action with respect to any individual patient on the basis of such information, and is prohibited from identifying, directly or indirectly, any individual patient in any report of such research

or evaluation, or otherwise disclosing patient identities in any manner.

(d) Opinion and description to be furnished program. Before any patient identifying information is required to be submitted by a program under the circumstances described in paragraph (c), the program shall be furnished--

(1) An opinion by the attorney general or other chief legal officer of the State to the effect that the conditions specified in paragraph (c) are fulfilled with respect to such program or with respect to all programs in such State similarly situated, and

(2) A description of the administrative procedures and physical limitations on access or other measures to provide for the security of the data, but such description shall not be in such detail as to furnish guidance for wrongful attempts to breach such security.

(e) Exclusiveness of procedures. No State or local governmental agency may require any treatment program to furnish patient identifying information to itself or any other recipient except in conformity with this section or §2.54. No Federal agency may require any treatment program to furnish patient identifying information to itself or any other recipient except in conformity with this section (other than paragraph (d)(1) thereof) or §2.54.

* * *

DISCUSSION

Rule 2.53 permits a State or Federal agency to set the minimum qualifications of the personnel performing the functions of audits, evaluation, and scientific research. Additionally, the State and Federal agency should establish organizational requirements and limitations on the categories of records that various personnel may review based on the need for the information and the particular qualifications of the personnel.

The agency has the responsibility of ensuring that there are "qualified personnel" or it runs the risk of having the audit be limited to financial and administrative data rather than having any access to review and audit any caseworker or counsellor notes, or any clinical records. Programs are, therefore, advised to organize their records so that administrative and financial records are separate and apart from clinical and patient records. By so doing, the program will avoid disclosure of any clinical information to those individuals conducting an audit who lack either the responsibility for, or appropriate training and supervision for, conducting scientific research, determining adherence to treatment standards, or evaluating treatment. (Rule 2.53(b).)

Finally, Rule 2.53(c) prohibits a State, agency, or political subdivision of a State from requiring as a "condition of funding, licensing or otherwise" a program recipient of their funds to participate in the furnishing of patient-identifying information for scientific research or long-term studies unless the following occurs:

1. The State agency or political subdivision is legally required to hold such information in confidence and is prohibited from using the information for any administrative, investigative, or other action against a patient.

2. The State agency or political subdivision complies with the Federal requirements of Rule 2.53(c), which prohibits the release of any patient-identifying information or identifying any patient directly or indirectly in any such evaluation, audit, or research report that is published.

3. Before any patient-identifying information is required, an opinion of the Attorney General or chief legal officer of the State shall be provided to the program, specifying that the conditions required by Rule 2.53(c) are met and a description shall be provided to the program of administrative procedures and security precautions that have been established to limit the access of individuals to the patient-identifying information in conformance with Rule 2.53(d)(2).

Points to Remember

- Before programs are required to participate in scientific research and long-term evaluation studies, the program should request that the State and/or political subdivision furnish an opinion of the Attorney General or chief legal officer of the State to the effect that 1) the State or political subdivision has the legal responsibility for securing and holding such information in confidence and, in accordance with Rule 2.53(c), that the agency is prohibited from taking any administrative, investigative, or other action against any patient and that no information on a patient will be directly or indirectly disclosed in any reports(s) resulting from such audit, evaluation, or scientific research; and 2) the State or political subdivision has established appropriate administrative procedures that will ensure the security of records and any patient identifying data.

- It is advisable for programs to establish appropriate procedures to ensure that State, Federal, and other entities which conduct audits, evaluation, and scientific research comply with the requirements of Rule 2.52.

§2.54: PATIENT IDENTIFYING INFORMATION IN CONNECTION WITH EXAMINATIONS

RULE

(a) *Definitions*. For the purposes of this section--

(1) The term "examination" means any examination to which this section is made applicable by parapraph (b) of this section.

(2) The term "examiner" means any individual or any public or private organization, including any Federal State, or local governmental agency, which conducts an examination to which this section applies.

(b) *Applicability*. This section applies to any examination of the records of a treatment program which is carried out for the purpose of or as aid to ascertaining the accuracy or adequacy of its finincial or other records, or the efficiency or effectiveness of its financial, administrative, or medical management, or its adherence to financial, legal, medical, administrative, or other standards, regardless of whether such examination is called an audit, an evaluation, an inspection, or by any other name.

(c) *Statement required for disclosure of patient identifying information in connection with examination*. No program may make, and no examiner may require, any disclosure of patient identifying information in connection with an examination unless the examiner furnishes to the program a written statement--

(1) that no record of patient identifying information will be made or retained by or on behalf of the examiner in connection with the examination without notice to the program in accordance with paragraph (c) (2) of this section, or

(2) setting forth the specific purpose for which a record of patient identifying information is being retained by or on behalf of the examiner, the location at which such information will be kept, and the name, official title, address, and telephone number of a responsible individual to whom any inquiries by the program about the disposition of such record should be directed.

(d) *Disposition of record of patient identifying information in connection with examination*. After any record of patient identifying information retained in connection with an examination has served its purpose, or within the time prescribed in paragraph (e) of this section, whichever is earlier, the examiner shall destroy or return to the program all records (including any copies thereof) containing patient identifying information which have been in its possession in connection with such examination.

(e) *Maximum time allowed for disposition*. The action required by paragraph (d) shall be completed--

(1) Except as provided in paragraph (e)(2) of this section not more than two years after the record was acquired by or on behalf of the examiner, or

(2) Where the record is needed in connection with a formal legal proceeding against the program commenced or to be commenced not more than two years after the record was acquired, and written notice to this effect is furnished to the program within two years after the record was acquired, not later than the termination of such proceeding.

(f) Notice of final disposition. When an examiner disposes of records as required by paragraph (d) of this section, or not later than the time prescribed by paragraph (e) of this section, whichever is earlier, the examiner shall furnish to the program concerned a written statement--

(1) That there has been compliance with this section and with the provisions of this part prohibiting any disclosure of patient identifying information from records held by auditors or evaluators, or

(2) Specifying the particulars in which there has been a failure of compliance.

* * *

DISCUSSION

Rule 2.54 authorizes the disclosure of patient-identifying information to an "examiner," for the purpose of conducting an "examination" of the program records and activities. However, Rule 2.54 emphasizes that no individual and or program in releasing information may make, and no examiner may require, any disclosure of patient-identifying information in connection with an examination unless the examiner furnishes to the program a written statement which stipulates:

1. That no record of patient-identifying information will be made or retained by or on behalf of the examiner in connection with the examination without notice to the program in accordance with (c)(2) of this section, or
2. Setting forth the specific purpose for which a record of patient-identifying information is being retained by or on behalf of the examiner, the location at which such information will be kept, and the name, official title, address, and telephone number of a responsible individual to whom any inquiries by the program about the disposition of such record should be directed.

The requirements of Rule 2.54 protects the confidentiality of patient-identifying information and prevents inadvertent disclosures to individuals who have no need for the information. Programs must be prepared to clarify and negotiate with the examiner for compliance with this rule.

Points to Remember

- Programs should organize their records so that financial or administrative matters can be reviewed without disclosing patient-identifying information or clinical data (except for audit verification).

- Only in certain specified circumstances may a State or local government agency require as a condition for funding, licensing, or otherwise, a program to provide records of patient-identifying information for scientific research or long-term evaluation studies.

- Confidence on the part of treatment program personnel in the integrity of auditing, evaluating, and regulatory processes is important for the effective functioning and supervision of the treatment system. Rule 2.54 fosters practices which will inspire and justify such confidence.

- This section permits the examination of the records of a treatment program by examiners for the purpose of determining the program's adherence to financial, administrative, medical, legal, or other standards.

- Prior to an examination which will make or retain records of patient-identifying information, the examiner must:

  1. Detail the specific purpose for which the patient-identifying information will be retained by or on behalf of the examiner;

  2. Indicate the location at which such information will be kept;

  3. Indicate the name, title, address, and telephone number of the person to whom inquiries might be made by the program about the disposition of such records;

  4. Ensure that no patient-identifying data will be kept for more than 2 years.

  (This section applies only to examinations utilizing patient-identifying information (see Rule 2.54(c)).)

- The examiner must give the program notice of final disposition of the records in accordance with Rule 2.54(f)(l) and (f)(2) of this section and, also, must tell the program whether or not he or she has complied with regulations, and which violations, if any, have occurred.

- An exception is made to the 2-year rule for disposition of records in the case of Rule 2.54(e)(2) where the record is needed in connection with a formal legal proceeding against the program commenced or to be commenced not more than 2 years after the record was acquired, and written notice to this effect is furnished to the program within 2 years after the record was acquired, not later than the termination of such proceeding.

- Examiners should be advised that the records of patient-identifying information secured pursuant to an audit must be destroyed or returned to the program within 2 years after this record(s) was acquired by or on behalf of the examiner (Rule 2.54(e)(l)).

- Programs are advised to establish a system to monitor compliance with Rule 2.54 by the examiner regarding the time allowed for disposition of records containing patient-identifying information.

Session 10

Rules 2.55-2.56

Session 10
Rules 2.55-2.56

§2.55 Supervision and Regulation of Narcotic Maintenance and Detoxification Programs

§2.56 Prohibition on Disclosure of Patient Identities from Research, Audit, or Evaluation Records

§2.55: SUPERVISION AND REGULATION OF NARCOTIC MAINTENANCE AND DETOXIFICATION PROGRAMS

RULE

...(b) Drug Enforcement Administration. Duly authorized agents of the Drug Enforcement Administration shall have access to the premises of registrants for the purpose of ascertaining compliance (or ability to comply) with standards established by the Attorney General under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) respecting the security of stocks of narcotic drugs and the maintenance of records (in accordance with section 307 of the Controlled Substances Act, 21 U.S.C. 827) on such drugs. Registrants shall maintain such records separate from and in addition to patients' clinical records required to be maintained under 21 CFR 310.505(d)(7)(iii), which shall not be available to such agents except as authorized under a court order in accordance with Subpart E of this part. Records maintained by registrants for the purposes of section 307 of the Controlled Substances Act (21 U.S.C. 827) need not identify patients by name, address, social security number, or otherwise except by an identifying number assigned by the registrant, but where such a system is used, the registrant shall maintain on a current basis a cross-index referencing each identifying number to the name and address of the patient to whom it refers. Upon request at any time and without advance notice, but subject to the provisions of § 2.54, such agents shall be granted immediate access to any such index. Such agents may use names and addresses so obtained strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information so obtained may not be compiled or used in any registry or personal data bank of any description.

(c) Food and Drug Administration. Duly authorized agents of the Food and Drug Administration shall have access to the premises of registrants and to all records maintained by registrants, for the purpose of ascertaining compliance (or ability to comply) with standards established by the Secretary of Health, Education and Welfare under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257a), sections 303(g)(1)

and 303(g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(1) and 823(g)(3)), and sections 505 and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and 371(a)). When necessary in the conduct of their duties, and subject to the provisions of § 2.54, agents may use names and addresses of patients strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information on patients obtained pursuant to this section or by any other compulsory process may not be compiled or used in any registry or personal data bank of any description. Except as authorized under this paragraph or by a court order granted under Subpart E of this part, (1) such agents may not, either orally or in writing, except in conversation with personnel of the registrant while on the premises of the registrant, identify any patient otherwise than by reference to an identifying number assigned by the registrant, and (2) such agents may not remove from the premises of the registrant any notes, documents, or copies thereof which contain patient identifying information.

(d) State drug law enforcement agencies. Duly authorized agents of any State drug law enforcement agency having jurisdiction and specific responsibility by statute or otherwise for the enforcement of criminal laws relating to controlled substances (as defined in the Controlled Substances Act) shall have access to the premises of any registrant for the purposes (with respect to corresponding provisions, if any, of State law) and subject to the restrictions and limitations set forth in paragraph (b) of this section, and subject to §2.54.

(e) State health authorities.

(1) Definition of "qualified State health agency". As used in this paragraph, the term "qualified State health agency" means an agency of State government (i) which has express legal responsibility to ascertain that registrants under its jurisdiction comply with appropriate treatment standards; (ii) which is legally and administratively separate from any agency of State government responsible for investigation of violations of, or enforcement of, criminal law generally or criminal laws relating to controlled substances; (iii) whose personnel are qualified by training or experience to conduct inspections of health care facilities to ascertain compliance with treatment standards; and (iv) whose personnel are by State law, or by published administrative directive enforced by effective sanctions, required to maintain the confidentiality of any information concerning the identity of patients which they may acquire in the course of their official duties.

(2) Access. Duly authorized agents of a qualified State health agency shall have access to the premises of registrants and to

all records maintained by registrants, for the purpose of ascertaining compliance (or ability to comply) with treatment standards (including those relating to quantities of narcotic drugs which may be provided for unsupervised use by individuals in treatment) established under State law. Such access, and the use of any information thereby obtained, shall be subject to the restrictions and limitations set forth in paragraph (c) of this section, and subject to §2.54.

* * *

DISCUSSION

The Federal Drug Enforcement Administration (DEA) and the State Drug Law Enforcement Agencies (SDLEA) referred to in Rule 2.55(b) and Rule 2.55(d) are permitted to have access to the "premises" of programs.

Authorized agents of DEA and SDLEA are permitted access to the premises of registered treatment programs and to certain records in order to determine compliance with standards established by the Attorney General and the State that cover the security of stocks of narcotic drugs (e.g., methadone) and the maintenance of drug records under the Controlled Substances Act.

Registered programs are required to maintain records of their stocks of narcotic drugs and records of patients receiving such drugs separate from and in addition to patients' clinical records. Programs cannot make thier clinical records available to agents except under court order.

Records maintained need not identify patients by name, address, or social security number, or in any other way except by identification number assigned by the program:

1. When an identification number is used, a program shall maintain a cross-index relating each number to name and address of patients.

2. Agents of DEA and SDLEA shall be granted immediate access to this index upon request and without advance notice.

Treatment programs are advised to ensure that neither the Federal Drug Enforcement Administration nor the State Drug Law Enforcement Agency are permitted by Rule 2.55(b) and (d) to have any access to treatment records without a court order. The program must take all reasonable precautions to avoid access to or disclosure of any patient information. In maintaining a registry or data bank in compliance with the Controlled Substances Act, 21 U.S.C. 827 Section 307 and Section 303(g)(2) of 21 U.S.C. 823(g)(2), the registrant may refrain from using names and addresses in this registry and instead use identifying numbers on each client receiving a controlled drug.

Rule 2.55(c) permits the Food and Drug Administration (FDA) access to he premises of registrants and all records maintained by a registrant on the patients served for the purpose of ensuring compliance with Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257a), Sections 303(g)(1) and 303(g)(3) of the Controlled Substances Act (21

U.S.C. 823(g)(1) and 823(g)(3)), and Sections 505 and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and 371(a)). The agents of the FDA have access to clinical records and may use names and addresses of patients in connection with their auditing or verifying of the program records.

Rule 2.55(e) permits a qualified State Health Agency which has "express legal authority and responsibility to ascertain that registrants under its jurisdiction comply with appropriate treatment standards" to have access to the premises and to all records maintained by the registrants to ensure compliance with treatment standards, and dispensing of narcotics and controlled substances. The agents of the State Health Agency must be persons who are qualified by experience and training to conduct inspections of health care facilities. These agents must maintain the confidentiality of all patient-identifying information.

Points to Remember

- Inasmuch as DEA Federal agents and State DLEA agents have access to the premises of registrant programs to verify compliance with the Controlled Substances Act Section 303(g)(2) of 21 U.S.C. 823(8)(2) and Section 307 21 U.S.C. 827, these agents are not authorized by Rule 2.55(b) and (d) to have access to clinical records. However, each registrant program must maintain a recordkeeping system of all the controlled drugs issued by the program.

- Authorized agents of FDA, DEA, the State Drug Law Enforcement Agency, and the State Health Agency may have access to the premises of a registrant program without any prior notice of such intention to visit.

- Registrant programs should request to examine the official identification of the agent. A record of the agent's name, office, telephone number, and supervisor should be maintained for future reference. If the agent fails to present an official identification, the program may refuse the agent access to the premises and the records of the registry until such time as the agent has produced an official identification.

- Only authorized agents of the FDA and the State Health Agency are:

    1. Permitted access to names, addresses, premises, and all records of the patient kept by the program to ascertain compliance with Federal and State laws;

    2. Permitted access to clinical as well as other records.

- Authorized, qualified agents of the State Health Agencies are permitted access to all records kept on the patient and program to ascertain compliance with treatment standards under State law, especially those regulations and laws relating to quantities of narcotic drugs that may be provided for unsupervised use by persons receiving treatment from the program.

- Treatment programs are well advised to provide all auditors, and examiners and authorized agents of FDA, DEA, the State Health Agency, and the State Drug Law Enforcement Agency, with a statement requiring that they are bound by Rule 2.55 of 42 C.F.R. Part 2 to maintain the confidentiality of all patient records.

- Treatment programs should maintain a registry on the record of controlled substances prescribed and given to patients in compliance with the Controlled Substances Act. This registry should be separate from other records. It should not contain any patient-identifying information, except a patient number to cross reference this record with the patient's regular file maintained by the agency. Of course, the registry data should indicate the type of drug, the quantity, and date the drug was prescribed and issued.

§2.56: PROHIBITION ON DISCLOSURE OF PATIENT IDENTITIES FROM RESEARCH, AUDIT, OR EVALUATION RECORDS

RULE

Where the content of patient records has been disclosed pursuant to this subpart for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State. This prohibition does not affect the accessibility of the original records under authority of a court order referred to in subpart E.

* * *

DISCUSSION

Rule 2.56 prohibits the recipient of patient-identifying information pursuant to Subpart D of the Federal regulations, for a management audit, financial audit, program evaluation, or scientific research, from disclosing information which directly or indirectly identifies any patient either voluntarily or in response to any legal suit or other legal process whether initiated at the local, State, or Federal level or by a patient, program, or other third party.

It should be noted that this rule does not affect the disclosure of the original patient records maintained by the program under the authority of a court order granted in accordance with the criteria and procedures set forth in Subpart E of the Federal regulations.

Points to Remember

- Under no circumstances can secondary records originally disclosed pursuant to Rules 2.52, 2.53, 2.54, and 2.55 of the Federal regulations be disclosed in any manner which would disclose directly or indirectly any patient-identifying information. See, however, the exceptions provided by Rule 2.52(b).

- The treatment program(s) should remind researchers, auditors, and evaluators of the requirement that reports prepared should not include any reference to patient identities.

Session 11

Subpart E
Court Orders

Session 11
Subpart E—Court Orders

§2.61 Legal Effect of Order
§2.62 Inapplicability to Secondary Records
§2.63 Limitation to Objective Data
§2.64 Procedure and Criteria in General
§2.65 Investigation and Prosecution of Patients
§2.66 Investigation and Prosecution of Programs
§2.67 Undercover Agents and Information

Learning Objectives

Upon completing this session, participants should be able to:

- Recognize the distinction between subpoena and court order (Rule 2.61).
- Know the process to be followed by the court in granting a court order for the release of patient information (Rules 2.62-2.64).
- Understand the process the court will utilize in granting an order for the release of patient-identifying information in connection with the investigation and prosecution of a patient in the program (Rule 2.65).
- Comprehend the process the court will utilize in granting an order for the release of information related to the investigation and prosecution of programs (Rule 2.66).

§2.61: LEGAL EFFECT OF ORDER

RULE

Subsection (b)(2)(C) of the sections which authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582) empowers the courts, in appropriate circumstances, to authorize disclosures which would otherwise be prohibited by subsection (a) of those sections. Subsection (b)(2)(C) operates only as a mechanism for the relief of the duty imposed by subsection (a) and not as an affirmative grant of jurisdiction to authorize or compel disclosures prohibited or privileged by other provisions of law, whether Federal or State. An order or provision of an order based on some other authority, or a subpoena, or other appropriate legal process, is required to compel disclosure. To illustrate, if a person who maintains records subject to this part is merely requested, or is even served with a subpoena, to disclose information contained therein in a manner prohibited in the absence of a court order, he must refuse such a request unless, and until, an order is issued under subsection (b)(2)(C). Such an order would remove *the prohibition, but could not, of its own force, require disclosure. If there were no subpoena or other compulsory process, or a subpoena had been issued but had expired or been quashed, the custodian of the records would have discretion as to whether to disclose the information sought unless and until disclosure were ordered by means of appropriate legal or administrative process, the authority for which would have to be found in some source other than subsection (b)(2)(C) of the sections authorizing this part.*

* * *

DISCUSSION

If a person who maintains drug or alcohol abuse patient records is merely requested, or even served with a subpoena, to disclose information from the records in a manner prohibited in the absence of a court order, he must refuse such a request unless, and until, an order is issued under subsection (b)(2)(c) of the sections that authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582). Such an order would remove the prohibition of subsection (a) of those sections, but could not, of its own force, require disclosure. In addition, even if a court order were issued but there were no subpoena or other compulsory process, or a subpoena had been issued but had expired or been quashed, the custodian of the records would have discretion as to whether to disclose the information sought unless and until disclosure were ordered by means of appropriate legal or administrative process.

Points to Remember

- A subpoena is a writ, or order issued by an officer of the court (i.e., lawyer, clerk of the court), under which one is directed to appear, or to produce documents or papers in one's possession or under one's control. Although a subpoena is issued under the authority of the court, Rule 2.61 requires that a treatment program refuse to turn over any information until a court order is obtained in compliance with Subpart E. A subpoena does not authorize disclosure, but a court order does.

- If a program is presented with a court order and a subpoena, the program is required to disclose the information requested. If the program objects or decides not to disclose the information requested, the program director should go to court to state the reasons for objecting to the disclosure of the information. Failure to respond to the court order and appear before the court may result in a citation for contempt of court being issued by the judge against the program director.

- It is advisable that, when a program is presented with a subpoena or a court order, an attorney be consulted for advice on handling this legal problem.

- Each program should establish appropriate procedures for responding to subpoenas and court orders. The staff should be advised that any subpoena or court order be referred to the program director or to his or her designee. This procedure would eliminate concern and confusion among program personnel and minimize the chances of unnecessary or unauthorized disclosure of patient-identifying information.

§2.62: INAPPLICABILITY TO SECONDARY RECORDS

RULE

The authority which subsection (b)(2)(C) of the sections which authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582) confers on courts to issue orders authorizing the disclosure of records applies only to records referred to in subsection (a) of such sections, that is, the records maintained by treatment or research programs which have patients, and not to secondary records generated by the disclosure of the subsection (a) records to researchers, auditors, or evaluators pursuant to subsection (b)(2)(B).

* * *

DISCUSSION

A court order may authorize treatment or research programs to disclose records that have patient-identifying information, but a court order does not apply to secondary records kept by program staff researchers, evaluators, or auditors that are obtained through disclosures from the program under Rules 2.52, 2.53, 2.54, and 2.55.

Points to Remember

- Rule 2.62 does not authorize disclosure of secondary records generated as a result of a disclosure to researchers, auditors, or evaluators.

§2.63: LIMITATION TO OBJECTIVE DATA

RULE

(a) Limitation to objective data. Except as provided in paragraph (b) of this section, the scope of an order issued pursuant to this subpart may not extend to communications by a patient to personnel of the program, but shall be limited to the facts or dates of enrollment, discharge, attendance, medication, and similar objective data, and may include only such objective data as

is necessary to fulfill the purposes for which the order is issued.

(b) Exception. When a patient in litigation offers testimony or other evidence pertaining to the content of his communications with a program, an order under this subpart may authorize the submission of testimony or other evidence by the program or its personnel.

* * *

DISCUSSION

Rule 2.63(a) limits the disclosure under a court order to objective data. This objective data is confined to the facts or dates of enrollment, discharge, attendance, termination, type of medication, and quantity and dosage of medication, and may include similar objective data necessary to fulfill the purposes for which the court order is issued and directed.

Rule 2.63(b) authorizes disclosure of testimony or other evidence when a patient in litigation offers testimony or other evidence pertaining to any communication he or she had with a program. Since the patient made this admission and disclosure during litigation (criminal or civil), the court may order the submission of this evidence and information by the appropriate personnel and the treatment program involved.

Points to Remember

- Generally, court orders can release only objective data recorded by the program.
- An exception to this rule exists when a patient involved in legal proceedings offers evidence in relation to the content of his or her communication with a program. Then, other interested parties may attempt to secure the content of the communication by seeking a court order authorizing the submission of this testimony or other evidence by the program or its personnel maintaining this information.

§2.64: PROCEDURES AND CRITERIA IN GENERAL

RULE

(a) Identity of patient. Applications for court orders to authorize disclosure of records pertaining to a known patient shall not use the real name of the patient unless the patient consents thereto voluntarily and intelligently. In the case of an ex parte application initiated by the patient, the application should be instituted in the name of a fictious person, such as

Jon Doe, unless the patient requests otherwise. The same procedure should be followed in the case of a separate proceeding held in conjunction with a pending criminal or civil action. Any court order should identify the patient fictitiously, and the disclosure of the patient's real name should be communicated to the program in such manner as to protect the confidentiality of the patient's identity.

(b) Notice. In any proceeding not otherwise provided for in this subpart, in which the patient or the program has not been made a party, each shall be given appropriate notice and an opportunity to appear in person or to file a responsive statement, deposition or other form of response consistent with local rules of procedure. The court shall give due consideration to any such statement, deposition or other response in exercising its discretion as to the existence of good cause and, if deemed necessary or desirable, consistent with local rules of procedure, it may order the program director to appear and give direct testimony.

(c) Hearings. All hearings and all evidence in connection therewith shall be held or taken in the judge's chambers, unless the patient requests an open hearing or the court determines that such hearing is consistent with the public interest and the proper administration of justice.

(d) Good cause. No order shall be issued unless the record shows that good cause exists, and in assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

(e) Need for disclosure. If other competent evidence or sources of information are available, the court should ordinarily deny the application.

(f) Adverse effects. If there is evidence that disclosure would have an adverse effect upon successful treatment or rehabilitation of the patient or would impair the effectiveness of the program, or other programs similarly situated, in the treatment or rehabilitation of other patients, the application should be denied unless the court finds that the adverse effects are outweighed by other factors.

(g) Content of order. Any order authorizing disclosure shall--

(1) Limit disclosure to those parts of the patient's record deemed essential to fulfill the objective for which the order was granted;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include any other appropriate measures to keep disclosure to a minimum for the protection of the patient, the physician-patient relationship and the treatment services.

(h) Applications not otherwise provided for. In any case not otherwise provided for in this subpart, application for an order authorizing disclosure of records to which this part applies may be made by any person who has a legally cognizable interest in obtaining such disclosure.

* * *

DISCUSSION

Rule 2.64 outlines procedures for the granting of a court order to disclose patient-identifying information and provides due process protection for both the patient and the program so that privacy and the physician-patient relationship are maintained.

The identity of the patient must be safeguarded as in Rule 2.64(a). The court order authorizing the disclosure will not use the real name of the patient unless the patient consents voluntarily and intelligently with no coercion. Therefore, any court order issued will normally use a fictitious name whether the proceeding is a criminal or civil action.

Where provided for under the Federal regulations and subpart E, the program and the patient should be given adequate notice of a pending court order or an application for a court order so that both the patient and the program will have an opportunity to be heard (see Rule 2.64(b)).

Rule 2.64(c) stated that all hearings and all evidence pertaining to an application for a court order shall be held in the judge's chambers. There are some exceptions, namely 1) when the patient (not the program) requests an open hearing, or 2) the court determines that it will be in the public interest and proper administration of justice to hold the hearing in open court.

Before a court order is granted under subpart E, the court will weigh whether good cause is established in the application. The court will also weigh the public interest and the need for disclosure against the potential damage to the patient, to the physician-patient relationship, and to the treatment services (Rule 2.64(d)). Also, if the court finds that there is any competent evidence or independent sources of information available to the applicant and the court, good cause will not be found and this information will not be released.

Finally, the court must weigh evidence of any adverse effects that granting the order will have on the successful treatment or rehabilitation of the patient, or on the effectiveness of the program or the treatment and rehabilitation of other patients.

When the court has decided to grant the court order authorizing disclosure according to this subpart E of the Federal regulations, the content of the order shall:

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1. Limit disclosure to those parts of the patient's record that are essential to fulfill the stated objective for which the order was granted.

2. Limit disclosure to those individuals whose need for the information was the basis of the order that was applied for. Only those persons who are identified in the order will have access to the information to be disclosed.

3. Limit the disclosure of information pursuant to the court order by including in the order any appropriate safeguards and measures that will protect the confidentiality of the patient, the physician-patient relationship, and the treatment services.

Points to Remember

- The right to a hearing in the judge's chambers as in Rule 2.64(c) is not an automatic or exclusive right.

- A court order will not be issued unless the court finds good cause after weighing the evidence provided by the applicant of the order and the objections raised by the patient and program.

- The court will weigh the adverse effects the granting of an order will have on the successful treatment of the patient and the ability of the program to provide services to other patients. The physician-patient relationship will be examined as the court assesses the need for disclosure of the information.

- Anyone requesting a court order must establish a need for disclosure of the information on the patient by the program, since there is no other independent way of obtaining competent information and the necessary information. If it can be established that the information requested is already in the possession of the person requesting the order or that other means of getting the same information are available, then the court should ordinarily deny the application for an order.

- An authorized court order by a competent court with competent jurisdiction should be a) confined to relevant and pertinent information, b) objective data, and c) specifically limit those persons who will have access to the information, d) provide for appropriate measures to maintain the confidentiality of the patient, and e) protect the patient's identity by using a fictitious name such as either Jane Doe or John Doe or some other assumed name.

Programs are advised to secure legal counsel to represent them at any hearing related to a pending court order. The legal procedures of a competent court will best be followed by an attorney. Proper legal representation at these hearings is important to the protection of the rights of the patient and to the treatment program. This legal representation might make the difference in granting a denial of a court order.

§2.65: INVESTIGATION AND PROSECUTION OF PATIENTS

RULE

(a) Applicability. This section applies to any application by an investigative, law enforcement, or prosecutorial agency for an order to permit disclosure of patient records for the purpose of conducting an investigation or prosecution of an individual who is, or who is believed to be, a present or former patient in a program.

(b) Notice. Except where an order under §2.66 is sought in conjunction with an order under this section, any program with respect to whose records an order is sought under this section shall be notified of the application and afforded an opportunity to appear and be heard thereon.

(c) Criteria. A court may authorize disclosure of records pertaining to a patient for the purpose of conducting an investigation of or a prosecution for a crime of which the patient is suspected only if the court finds that all of the following criteria are met:

(1) The crime was extremely serious, such as one involving kidnapping, homicide, assault with a deadly weapon, armed robbery, rape, or other acts causing or directly threatening loss of life or serious bodily injury, or was believed to have been committed on the premises of the program or against personnel of the program.

(2) There is a reasonable likelihood that the records in question will disclose material information or evidence of substantial value in connection with the investigation or prosecution.

(3) There is no other practicable way of obtaining the information or evidence.

(4) The actual or potential injury to the physician-patient relationship in the program affected and in other programs similarly situated, and the actual or potential harm to the ability of such programs to attract and retain patients, is outweighed by the public interest in authorizing the disclosure sought.

(d) Scope. Both disclosure and dissemination of any information from the records in question shall be limited under the terms of the order to assure that no information will be unnecessarily disclosed and that dissemination will be no wider than necessary. Under no circumstances may an order under this section authorize a program to turn over patient records in general, pursuant to a subpoena or otherwise, to a grand jury or a law enforcement, investigative, or prosecutorial agency.

(e) Counsel. Any application to which this section applies shall be denied unless the court makes an explicit finding to the effect that the program has been afforded the opportunity to be represented by counsel independent of counsel for the applicant, and in the case of any program operated by any department or agency of Federal, State, or local Government, is in fact so represented.

* * *

DISCUSSION

Rule 2.65 applies when an application for a court order is made to disclose information to an investigative, law enforcement, or prosecutorial agency, for the purpose of conducting an investigation or prosecution of an individual who is (or is believed to be) a present or former patient in a program. This rule requires that the following procedures be followed:

1. The program whose records are being sought must be notified within reasonable time of the application for a court order. The program must be given an opportunity to appear personally or by counsel and present evidence regarding this request.

2. The right to legal counsel is afforded the program, and in the case of a Federal, State, or local entity, legal counsel is also required. An application for a court order will be denied unless the court hearing such a request finds explicit evidence that the program or governmental entity has been given the opportunity to be represented by counsel.

3. The court must be satisfied that the information sought cannot be secured by any other means and that this information will be material, relevant, and of substantial value in connection with the investigation and/or prosecution.

4. A court order pursuant to Rule 2.65 may not authorize a program to disclose general information about a patient. The dissemination and disclosure of the information from the patient's record must be limited to the information that is necessary in light of the scope of the order issued.

Points to Remember

When application for a court order is made under this section, the following rules apply:

- Except where an order under Rule 2.66 is sought in conjunction with an order under this section, the program must be notified of the application and be given an opportunity to testify.

- The program has a right to be represented by counsel.

- The programs funded by Federal, State, or local government must be represented by counsel.

The court may not authorize a program to turn over records in general. Information must be limited under the terms of the court order.

The following requirements must be met before a court may require disclosure:

- The crime must be extremely serious.
- There must be no other practical way of obtaining the information sought.
- There must be a reasonable likelihood that the records disclosed will substantially aid in the investigation.

§2.66: INVESTIGATION AND PROSECUTION OF PROGRAMS

RULE

(a) Applicability. This section applies to any application by an administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency for an order to permit disclosure of patient records or the making of copies thereof (including patient identifying information) for the purpose of conducting an investigation or an administrative or judicial proceeding with respect to any program or any principal, agent, or employee thereof in his capacity as such.

(b) Notice. An application under this section may, in the discretion of the court, be granted without notice, but upon the implementation of any order so granted, the program shall be afforded an opportunity to seek the revocation or amendment of such order.

(c) Scope. Both disclosure and dissemination of any information from the records in question shall be limited under the terms of the order to assure that patient identities will be protected to the maximum practicable extent, and that names and other identifying characteristics of patients are expunged from any documents placed in any public record. No information obtained pursuant to an order under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under §2.65.

* * *

DISCUSSION

When an application is made for disclosure of patient information pursuant to an administrative, judicial, or investigative proceeding of any program or its employee(s), at the discretion of the court, the application for disclosure may be granted without notice to the program. However, if an order is granted under these circumstances, the program must be given an opportunity to seek revocation or amendment to the order. The program or its legal counsel may raise any reasonable objection to the granting of this order.

In all instances, a court order under Rule 2.66 should limit disclosure to the information relevant and necessary to accomplish the purpose of this order. The order shall also protect the patients' identities to the maximum degree and extent practical. The party or parties receiving information disclosed under such an order will be prohibited from using it to conduct an investigation or prosecution of a patient or even as a basis for securing a court order authorized under Rule 2.65 relating to "Investigation and Prosecution of Patients."

Points to Remember

- A court order for the disclosure of information under Rule 2.66 may be granted without notice to programs. However, the program must be allowed the opportunity to seek revocation or amendment of the order before the order is fully executed.

- An order so granted should ensure that maximum protection is provided to protect patient identities.

- Any information that is disclosed under this section cannot be used to prosecute or investigate patients or to secure a court order under Rule 2.65 of this subpart E.

- An application for a court order issued under Rule 2.66 makes it possible for any local, State, or Federal administrative, regulatory, supervisory (Single State Agency for alcohol or drug abuse activities), investigative, law enforcement, or prosecutorial agencies, to seek disclosure of patient records, including the making of copies for the purpose of conducting an investigative, administrative, or judicial proceeding.

- An order granted under Rule 2.66 could authorize disclosure for an investigation and/or judicial proceeding against:

    - an employee
    - an agent of the program
    - a principal of the program
    - a program

§2.67: UNDERCOVER AGENTS AND INFORMANTS

RULE

(a) Applicability. This section applies to any application by an administrative, regulatory, supervisory, investigative, or law enforcement agency for an order to permit such agency to have an undercover agent or informant in a program under circumstances which would otherwise be prohibited under §2.19.

(b) Notice. An order under this section may be granted without notice where the criminal conduct for the investigation of which it is granted is believed to be carried on by the program director or by any employee or agent of the program with the knowledge of the program director or under such circumstances that in the exercise of reasonable care the program director should know of such conduct. Under any other circumstances, an order under this section may be granted only after the program director has been afforded notice and opportunity for hearing.

(c) Criteria. An order under this section may be granted only where there is reason to believe that a program or any principal, agent, or employee thereof is engaged in serious criminal misconduct, and that other means of securing evidence of such criminal misconduct are not available or would not be effective.

(d) Scope. An order granted pursuant to this section may authorize the use by the applicant of an undercover agent or informant, either as a patient or as an employee, of the program in question.

(e) Time periods. An order under this section may not authorize the use of an undercover agent for an initial period exceeding 60 days. At any time prior to the expiration of such 60-day period, the applicant may apply for an order extending such period for an additional period not to exceed 60 days, but in no event may the use of an undercover agent in any program be authorized for more than 180 days in any period of 12 consecutive months.

(f) Duty of agent. Except to the extent expressly authorized in an order under this section, which shall be limited to disclosure of information directly related to the purpose for which the order is granted, an undercover agent or informant shall for the purpose of this part be deemed an agent of the program within which he is acting as such, and as such shall be subject to all of the prohibitions of this part applicable to disclosures of any information which he may acquire.

* * *

DISCUSSION

Rule 2.67 applies to any application for the placing of an undercover agent or informant in a program under circumstances which would normally be prohibited under Rule 2.19 of the Federal regulations.

An order may be granted without any notice to the program in those instances where the serious criminal misconduct related to the investigation is attributed to the program director or an employee or agent of the program acting with the knowledge of the program director.

When such an order is granted, it will authorize the use of an undercover agent for an initial period of up to 60 days. The applicant must apply for an extension of such a period prior to the expiration of the 60-day period. The total number of extensions may not exceed 180 days during any 12 consecutive months. Except as expressly authorized by the court order, an undercover agent or informant is subject to all the provisions of this part applicable to disclosures of any information which he or she may acquire.

Points to Remember

- A court order may authorize the use of informants and undercover agents either as patients and/or employees of the program.

- The order may not authorize the use of an undercover agent or informant for an initial period exceeding 60 days. Before the order expires, the applicant for the original order may apply for an extension for an additional 60 days. An undercover agent cannot be authorized for use in any program for more than 180 days in any period of 12 consecutive months. Except as expressly authorized by the court order, an undercover agent is subject to all the provisions of this part applicable to disclosures of any information which he or she may acquire.

- The applicant for such an order must establish that a program, or any principal, agent, or employee thereof, is engaged in serious criminal misconduct. Furthermore, the applicant must establish that no other effective means is available to secure evidence of such criminal misconduct.

Outline of Court Order Authorizing Disclosure of Alcohol or Drug Abuse Patient Records Under 42 C.F.R., Rules 2.61-2.64

1. In accordance with (U.S. code citation to the drug or alcohol confidentiality statute, as appropriate)[1] and (the pertinent sections of the regulations, e.g., Subpart E of 42 C.F.R. Part 2), this court finds:

(a) That the record shows good cause (as required in § 2.64(d)) for the disclosure of certain objective data (limitations set forth in § 2.63 (a)) specified below, pertaining to John Doe (pseudonym used in accordance with the intent of §2.64(a) and (g)(3)) for the purpose of ______________________ ____.

(b) (The specific facts necessitating disclosure) outweigh the possible injury to the patient, etc. (follow the language set forth in §2.64 (d) and in subsection (b)(2)(C) of the authorizing statute) and outweigh the following adverse effects upon the successful treatment or rehabilitation of the patient, etc. (follow the language set forth in § 2.64(f)) ___________________________ ____.

(c) (Optional) Further, that disclosure will benefit the patient as follows: ____; or that disclosure will benefit the effectiveness of the treatment program or other programs similarly situated as follows: ______________________________.

2. It is therefore ordered that (the program and/or name(s) of responsible program staff) is (are) authorized, in accordance with 42 C.F.R. §2.61-2.64 and (the appropriate U.S. Code citation) to disclose to this court and/or to the following named parties who have a need to know this information: _____ ____; which is essential to fulfill the above-described objective(s). These persons (may not redisclose the information, or may redisclose the information only as follows: ____).

To the extent the disclosed information is to be retained by the court, in accordance with §2.64(g)(3), it will be kept in a sealed record.

(Optional) Except pursuant to an authorizing court order issued in accordance with §2.65, no information disclosed pursuant to this order may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

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[1] 42 U.S.C. 4582 for disclosures of alcohol abuse patient records.
21 U.S.C. 1175 for disclosures of drug abuse patient records.

Exercise VII: Court Orders and Investigation of Patients, Rule 2.65

Problem

Thomas Halpert was enrolled in the Westwood Drug Treatment Program's inpatient facility. During the period of his involvement with the program, he was arrested on the charge of assault with a deadly weapon. It was discovered that during his enrollment, a series of assaults occurred within close proximity to the program premises. Mr. Halpert was implicated in these assaults.

The Office of the State prosecutor has filed an application for a court order authorizing the disclosure of information pertaining to Halpert's attendance and progress within the program.

Products

1. Individually prepared outline of procedures to be followed by the program, including both legal and disclosure procedures.
2. A single procedural outline to be followed by the program, prepared by the group and recorded on newsprint.

Directions

1. Meet in your assigned small group. Choose a timekeeper, recorder, and spokesperson.

   Timekeeper: Allow about 10 minutes for the individual work, 5 minutes for exchange of work and feedback, and 10 minutes for the group's procedural outline.

   Recorder: When the group develops its outline, print the procedures clearly on newsprint.

   Spokesperson: Be prepared to present/clarify the group's work. Bring newsprint to the main meeting room; display. You will have about 5 minutes to present.

2. Working individually, outline the procedures to be followed by the program, considering both legal and disclosure procedures. (10 minutes)
3. Exchange outlines with another person in your group. Discuss whether the conditions that exist are consistent with those requirements that must be met before a court order is obtained. If appropriate, revise your outlines. (5 minutes)
4. Draw up a single procedural outline representing the best thoughts of the group on both legal and disclosure procedures. Be specific. Put this outline on newsprint.

Trainees are urged to seek help, if needed, from the training staff.

Exercise VIII: Court Orders and Investigation of Programs, Rule 2.66

Problem

The director of Project Seek-Out is suspected of mishandling monies appropriated for program operation. Because of the nature of the illegality, a Federal prosecutorial agency has filed an application for the disclosure of the financial records of the program.

The financial information sought concerns the specific area of monies spent for laboratory tests administered to all program clients. These services are provided by a qualified service organization that was contracted for these specific tests.

Products

1. Individually prepared outline of procedures to be followed in compliance with Rule 2.66.

2. Group-prepared composite procedural outline, printed on newsprint.

Directions

1. Meet in your assigned small group. Choose a timekeeper, recorder, and spokesperson.

   Timekeeper: Allow 5 minutes for individual work, 5 minutes for exchange and feedback, and 5 minutes for the composite group outline.

   Recorder: When the group develops its composite outline, print the procedures clearly on newsprint.

   Spokesperson: Be prepared to present/clarify the group's work. Post newsprint in main meeting room. You will have about 3 minutes to present.

2. Working individually, develop an outline of procedures to be employed in compliance with Rule 2.66. (5 minutes)

3. Exchange individually prepared procedural outlines. Discuss the issues of 1) the program's responsibility toward client confidentiality during the audit; 2) the appropriate safeguards to ensure confidentiality; and 3) responsibilities and limitations of the court with respect to the use of program records. (5 minutes)

4. Working within your specified group, draw up one composite procedural outline. Make sure that your outline responds to the three issues raised in your exchange discussion. Put this outline on newsprint. (5 minutes)

Trainees are urged to seek help, if needed, from the training staff.

Session 12

Issues in Confidentiality

Session 12
Issues in Confidentiality

Liability Insurance
Legal Counsel
Physical Security of Records
Written Procedures
Staff Education
Education of the Governing Body of Each Program
Interagency Cooperation
State and Federal Monitoring
Amendments to State and Federal Laws on Confidentiality
Ethical Considerations

SUMMARY AND PRACTICAL APPROACHES TO CONFIDENTIALITY ISSUES

Liability Insurance

Rule 2.14 of the Federal Regulations on Confidentality of Alcohol and Drug Abuse Patient Records imposes a fine of not more than $500.00 for a violation that is a first offense. The penalty means that an individual staff member might, if found in violation, be assessed a fine. Whether or not this penalty could be found applicable to a program or entity is unclear. It will depend on the ruling of the court.

Although it is questionable whether malpractice insurance would cover the assessment of this fine (which has been determined to be a criminal penalty by the Department of Health, Education, and Welfare Office of General Counsel), all treatment personnel and key administrative staff may wish to consider obtaining malpractice insurance covering violations of patient(s) confidentiality.

Legal Counsel

It is advisable for all programs and entities to seek the advise of legal counsel to review their program guidelines, and to respond to questions requiring a legal opinion and interpretation of the Federal and State laws and regulations. This consultation is especially important when responding to court orders or subpeonas for the disclosure of patient information.

Physical Security of Records

Federal Rule 2.17 mandates that all patient information be kept in a secured room or in secured cabinets.

- A system should be established for retrieval of these records.
- A recordkeeper should be available to manage these records.
- Access to patient records should be limited.

- Failure to keep records in the secured fashion required of the regulations will result in a violation of Federal laws and rules.

Written Procedures

Rule 2.17 requires that a written procedure should be in effect regulating and controlling access by those members of the staff whose responsibilities require such access and providing for accountability.

Programs are advised to prepare written procedures on the confidentiality of alcohol and drug abuse patient records. These should be incorporated into the personnel policies of the program. Additionally, the written policies and procedures should form the basis for on-going orientation and education of staff. It is advisable to consult an attorney who will review these policies and procedures for compliance with Federal and State laws and regulations.

Staff Education

Staff education should be an on-going process for the effective implementation and enforcement of the basic laws, regulations, and internal procedures on confidentiality. The present personnel policies should be expanded to include the program's confidentiality policies and procedures.

The following areas should be incorporated in any staff education program:

- The Federal Rules as embodied in the Federal Register, Volume 40, No. 127, entitled "Confidentiality of Alcohol and Drug Abuse Patient Records";
- The relevant State laws and regulations on confidentiality;
- The program's policies and procedures on confidentiality;
- Any specific cases that have been decided by the courts in the State.

In summary, staff education is an indispensable activity for the programs to undertake on an on-going basis. Since violations of the confidentiality rules and regulations result in personal liability, it is necessary for each staff member to receive adequate information on the rules and regulations pertaining to confidentiality of alcohol and drug abuse patient records.

Education of the Governing Body of Each Program

The governing body of each program or entity should be informed regarding the requirements of the Federal and State laws and regulations. This education process should be set up to alert the governing body to the fact that members might be held liable for any breach of the Federal and State laws and regulations. Special attention should be given to:

- Approval of the official written policies and procedures pertaining to confidentiality of patient records;

- Review of existing liability insurance policies covering violations of patient(s) confidentiality;
- A system for updating and amending of the written policies.
- A system for recording, hearing, and resolving basic complaints on violations of confidentiality of patient records.

Interagency Cooperation

The Rule 2.11(n) concerning qualified service organizations and Rule 2.34 on the Central Registry and other relevant sections of the rules provide agencies with the opportunity to share, refer, and receive information without violating the rights of the patients or any Federal or State law. The very foundation of any interagency collaboration should be the entering in of an agreement between the two agencies. This agreement should embody the legal requirements of Rule 2.11(n) on qualified service organizations, when appropriate.

State and Federal Monitoring

It should be noted that the trend is towards establishing specific systems for the enforcement of the confidentiality laws and rules.

Program monitoring by State and Federal agencies has been broadened to include examination of the program policies, procedures, and records to ascertain whether there has been compliance with the Federal and State laws and regulations on confidentiality of alcohol and drug abuse patient records.

Some States have delegated the responsibility for monitoring enforcement to substance abuse program staff, the Attorney General, or the Chief Counsel for Substance Abuse. For Federal Government, the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism have recently set up units for compliance. These units will answer questions on enforcement of the confidentiality laws and regulations.

AMENDMENTS TO STATE AND FEDERAL LAWS AND REGULATIONS ON CONFIDENTIALITY

As case law and administrative decisions develop in this area, amendments will probably be made to the laws and regulations at both the Federal and State levels. In order to keep up with changes, it is necessary to review Federal and State legislative publications and the Federal Register for changes in the rules.

Ethical Considerations

Programs have an ethical responsibility to educate patients/clients in their rights to confidentiality of their oral and written records as required by Federal and State laws and regulations. Although research of the Federal and State laws on confidentiality indicates that no express requirement has been written into any of these laws or regulations that programs educate their patients/clients on their rights to confidentiality, an implicit ethical requirement is apparent.

The illustration on patient education is intended to provide the reader with a conceptual framework for implementing an education program for patients. The following guidelines should be followed:

- Education of patients on confidentiality should be an on-going process.

- Education should begin at "intake."

    - The patient should be informed about program rules and regulations regarding confidentiality of patient records. The various consent forms should be reviewed with the client.

    - The client should be told about his/her responsibility to follow the confidentiality procedures in addition to maintaining the confidentiality of any oral or written records and communication about himself or any other patient in the program.

    - The program should get the patient to stipulate the persons to whom the program can acknowledge his or her absence.

    - If the program uses a central registry, the client should be informed of this fact and the necessary consent form should be completed.

    - The qualified service agreement should be discussed with the client regarding those programs and entities with whom there is an existing qualified service agreement.

Active Clients

The active clients should receive specific education around the program's guidelines on confidentiality in the following areas:

- Release of information in general;

- Required consent forms according to Rule 2.3l;

- Traveling clients;

- Incarcerated clients;

- Procedures regarding group counseling and individual counseling;

- Emergency procedures and the requirements in Rule 2.5l.

Terminated Clients

- The terminated clients' records should be maintained in a confidential manner.

- A procedure should be established for handling requests for records of terminated clients. Special steps should be taken to verify the identity of the requestor to ensure that it is the client or someone duly authorized to request this release under Federal and State laws.

- The records of terminated clients should be maintained in a secured room and in locked cabinets which are fireproof. The program should limit access to these records.

- The records of terminated clients should be retained for the period specified by State alcohol and drug abuse laws and regulations. It should be noted that the Federal laws and regulations do not spcify the period of retention of terminated client records. Recommended procedure is that terminated patient records be maintained for a minimum of 5 years from the official recorded date of said termination.

Summary

A concerted effort is needed in the area of patient education of confidentiality. We have to be reminded that programs must first get their procedures written up and staff fully trained to implement these procedures. Education of patients should be a gradual and on-going process. Programs should set up a mechanism to deal with internal complaints of clients regarding violations of the confidentiality of their patient records. The program's attorney should be available to provide legal advice on any matters related to confidentiality.

Session 13

Posttest and Closing Remarks

Session 13
Posttest
Confidentiality Regulations Review Test

The following is a brief test of major points in the Federal confidentiality regulations covered by this course. The test is intended as an assessment tool to determine how well you have grasped the major issues surrounding the confidentiality regulations and their application. After completing this posttest, check your answers. If you have missed any, it would be helpful for you to review these areas for clarification.

The first 17 questions are True or False. Circle the letter on your answer sheet to indicate whether each statement is true or false.

TRUE OR FALSE

1. Qualified personnel of the Food and Drug Administration may audit records of a narcotics maintenance program, and have access to patient-identifying information, without the written consent of the patient.

   T F

2. The parent of a minor communicates his permission for his child to enroll in a drug treatment program in a State where parental consent is required. Later the parent contacts the program for information pertaining to the minor's treatment. The program cannot communicate this information without the minor's written consent.

   T F

3. Patients may not be issued and required to carry identification cards on the premises of a given program to be used for the purposes of correct recording of medication and positive identification.

   T F

4. The only conditions under which consent for disclosure of information terminates are with a written revocation of consent or when the conditions of the consent have been fulfilled.

   T F

5. According to the regulations, tax-exempt organizations are bound under the Federal confidentiality regulations.

   T F

6. Drug or alcohol abuse treatment programs that receive funding by the State can be required to make available patient records for the purpose of long-term evaluation studies.

   T F

7. Consent forms that conform to the eight points that are required by law are valid even when there is false information of which the program is unaware.

T F

8. Disclosures to qualified medical personnel are authorized for patients in instances of a genuine medical emergency with the provision that a memorandum be recorded by the program making the disclosure.

T F

9. When served with a subpoena, an individual who is responsible for the maintenance of patient records must disclose the specified information in the subpoena.

T F

10. An undercover agent or informant may be placed within a program by the court for the purpose of investigating illegality for an initial period of 90 days.

T F

11. According to the regulations, any program registered under Rule 303(g) of the Controlled Substances Act may be required, without a court order, to provide clinical information pertaining to the records of any patient enrolled in a narcotic maintenance or detoxification program to duly authorized agents of the Drug Enforcement Administration.

T F

12. Third-party payers are eligible to receive and maintain records on the identity of individuals receiving treatment for which they (third-party payers) have been contracted to pay.

T F

13. Interchange of information entirely within the Armed Forces, and within those components of the Veterans Administration furnishing health care to veterans, or between such components and the Armed Forces, is not subject to the provisions of 21 U.S.C. 1175 and 42 U.S.C. 4582.

T F

14. It is not in violation of the Federal regulations for a program to make a disclosure with respect to an applicant for treatment to a permissible central registry.

T F

15. An attorney asks a program for information regarding his client who is enrolled in the program. The program requests that the consent form

be signed by the client and endorsed by the attorney. Is the program correct?

T F

16. A former employee may release information about a former client which is not contained in the client record.

T F

17. A law enforcement officer may be enrolled in a treatment program for the purpose of receiving treatment for his or her own alcohol or drug abuse problem, providing, however, his or her status as a law enforcement officer is known to the program director.

T F

MULTIPLE CHOICE

The next 10 questions are multiple choice. Blacken the letter of your answer sheet to indicate the single best answer to each question.

18. When a disclosure has been made with regard to a client, the disclosure must be accompanied by a statement to the effect that further disclosure by the recipient is prohibited. The exception to the rule pertaining to disclosure exists when:

    a) there is a provision for a general authorization included within the release form

    b) the disclosed information is to be used by an employment agent or agency (pursuant to written consent of the client which explicitly provided for redisclosure) for the purpose of releasing information to potential employers

    c) the recipient of the disclosed information is an evaluation agent who reports summary data that contain minimal patient-identifying information

    d) none of the above

19. An evaluation agency that has legally received disclosure patient data for analysis is within established legal bounds in releasing information:

    a) after a court order has been issued and a good cause hearing has taken place

    b) but the report should not identify any patients' names

    c) either of the above

    d) neither of the above

20. In cases where the patient has given written consent for a program to disclose information to a potential employer, a program director is within the bounds of the law for refusing to release such information when:

    a) it is used as criteria for decisions surrounding denial of employment or promotion of an individual receiving treatment

    b) the information requested has little bearing on the job

    c) both of the above

    d) none of the above; the program must release the information when there is a written consent

21. A central registry should receive information from member programs with respect to any patient when:

    a) there is an application for treatment

    b) treatment has been terminated

    c) the type and/or dosage of the medication has been changed

    d) all of the above

22. In instances of prosecutorial or investigative action, a court may authorize a program to disclose patient records in crimes of:

    a) rape

    b) burglary

    c) larceny

    d) fraud

23. When a program is acquired by another program and there has been no consent secured from the patients of the acquired program for the transferral of records, the records should be:

    a) cleared of patient-identifying information

    b) released to the patients under the Freedom of Information Act

    c) destroyed

    d) transferred, since Federal regulations do not require patient consent for the transfer of records

24. Which of the following items is not required on a consent form?

    a) signature of the client

    b) statement of the provision for revocation of consent

c) date on which the consent is signed

d) statement regarding prosecutorial reprisal for unauthorized disclosure that includes the nature of the legal action and fines

25. You were convicted last year and fined $500 for improperly releasing the name of a patient in your alcoholism treatment program. You have just been found guilty of failure to maintain proper security of patient records in your drug abuse treatment program:

a) the judge can fine you up to $500

b) the judge can fine you up to $5,000

c) the judge may impose a $5,000 fine and imprisonment under the felon clause of the regulations

d) none of the above

26. When a nonemergency situation exists, the family of a patient may receive information when:

a) there is a formal application in writing from the legal counsel to the program that is maintaining the necessary information

b) if, in the judgment of the person responsible for treatment, the disclosure will be helpful to the patient

c) only when there is formal written consent given by the patient

d) whenever the patient and family members are together

27. In certain situations, the Federal regulations do not restrict disclosures of patient information. One such situation is a disclosure to:

a) the director and/or other program personnel responsible for treatment

b) the patient's doctor and attorney

c) the spouse and friends of an adult patient

d) none of the above

Posttest Answer Sheet

TRUE OR FALSE

1. T F
2. T F
3. T F
4. T F
5. T F
6. T F
7. T F
8. T F
9. T F
10. T F
11. T F
12. T F
13. T F
14. T F
15. T F
16. T F
17. T F

MULTIPLE CHOICE

18. A B C D
19. A B C D
20. A B C D
21. A B C D
22. A B C D
23. A B C D
24. A B C D
25. A B C D
26. A B C D
27. A B C D

Federal Regulations Key to Posttest

QUESTION NUMBER	FEDERAL REGULATIONS
1	2.55
2	2.1[illegible]
3	2.20
4	2.31
5	2.12
6	2.53
7	2.31
8	2.51
9	2.61
10	2.67
11	2.55
12	2.37
13	2.12
14	2.34
15	2.35
16	2.22
17	2.19
18	2.32
19	2.52
20	2.38
21	2.34
22	2.65
23	2.21
24	2.31
25	2.14
26	2.36
27	2.11(p)

Evaluation Feedback Questionnaire

TRAINING PROGRAM: Confidentiality of Alcohol and Drug Abuse Patient Records

PROGRAM DATES: ________________ LOCATION: ____________________

TRAINER(S): ____

In order to assess the effectiveness of the training programs we are delivering, and to gather feedback that will help us to plan for improved deliveries, we routinely distribute this questionnaire to all participants. To maximize the chances that you will give us your honest views, we do not ask you to identify yourself. Thank you for your cooperation.

Please rate this program in certain key areas. For each category we ask you to give a numerical score and to write down comments you would like to make. Please make your ratings using a scale of 100--as if you were grading an exam. Thus, you would use these guidelines:

EXCELLENT - Score between 90-100

GOOD - Score between 80-90

SATISFACTORY - Score between 70-80

MARGINAL - Score between 60-70

UNSATISFACTORY - Score between 0-60

Your ratings will be used to derive an overall numerical assessment of this program.

We also provide space for personalized comments. Your written response will be read carefully by the trainers and used to improve future programs.

1. Rate the extent to which the program objectives were met. ____________
   COMMENTS AND SUGGESTIONS:

2. Rate the extent to which the course materials (manual, etc.) were effective aids for achieving the objectives. ____________
   COMMENTS AND SUGGESTIONS:

3. Rate the quality of the staff's presentation, as a group. ____________
COMMENTS AND SUGGESTIONS: (Feedback about specific staff members is encouraged.)

4. Rate the extent to which you have understood the material presented. ____________
COMMENTS AND SUGGESTIONS:

5. Rate the extent to which you have developed new skills by attending this workshop. ____________
COMMENTS AND SUGGESTIONS:

6. Rate the extent to which you think you will be able to apply the new skills you have learned in your own personal work situation. ____________
COMMENTS AND SUGGESTIONS:

7. Rate the quality of the administration and logistical arrangements of the program. ____________
COMMENTS AND SUGGESTIONS:

8. Rate the program as a whole. ____________
COMMENTS AND SUGGESTIONS:

APPENDIX

Confidentiality of Alcohol and Drug Abuse Patient Records
Federal Law Title 42—Public Health
(Federal Register, Volume 40 C.F.R. 27802, July 1, 1975)

federal register

TUESDAY, JULY 1, 1975

WASHINGTON, D.C.

Volume 40 ■ Number 127

PART IV

THE NATIONAL ARCHIVES OF THE UNITED STATES • 1934 •

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

■

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

General Provisions

REPRINTED BY THE
U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND
MENTAL HEALTH ADMINISTRATION

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL PROVISIONS

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

On May 9, 1975, the Department of Health, Education, and Welfare and the Special Action Office for Drug Abuse Prevention published in the FEDERAL REGISTER (40 FR 20522) a notice of proposed joint rulemaking setting forth a proposed new Part 2 of Title 42 of the Code of Federal Regulations governing the confidentiality of alcohol and drug abuse patient records.

Interested persons were invited to submit written comments, views, or arguments with respect to the proposed regulations within 30 days of the date of publication of that notice. All comments so submitted were carefully considered, and at various stages in the rulemaking process, the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected by the proposed regulations were consulted.

As finally adopted and set forth hereinafter, the regulations contain two major substantive changes from the May 9 proposal. The separate treatment of funding sources and third-party payers (§§ 2.21 and 2.37 of the proposed regulations) was abandoned as unworkable, primarily because the prohibitions which the proposed regulations would have placed on funding sources would have directly conflicted with requirements which have been proposed in implementation of Title XX of the Social Security Act (see proposed 45 CFR 228.63, 40 FR 16802, 16809, April 14, 1975). In lieu of this approach, § 2.37 has been revised to provide that funding sources and third-party payers maintaining drug or alcohol abuse patient records are subject to restrictions upon disclosure to the same extent and in the same manner as any other entity maintaining records which are within the scope of the authorizing legislation and this Part.

The other major change is in the area of criminal justice system referrals, and the grounds for the rules finally adopted are set forth in the basis and purpose section (§ 2.39–1) pertaining thereto. In connection with that change, it must be frankly acknowledged that the arguments set forth in the corresponding basis and purpose section (§ 2.40–1) of the May 9 proposal have merit. The final rule may in certain instances result in a compromise of the treatment process, if judges or other authorities in the criminal justice system overreact to information whose communication is allowed under the final rules but would have been prohibited under the proposed rules.

Against such an adverse effect, however, there must be weighed the very real advantage which genuine cooperation between community social service systems and the criminal justice system can yield for those whose lives are crippled and scarred by the consequences of their own criminal conduct. Governmental responses based on a pure medical model have not met with noticeably greater success than those based on a purely punitive approach, and it would be tragic if these rules were so constructed as to become a barrier to the development of better ways to deal with those who are caught up in a pattern of seriously antisocial behavior.

In addition to the foregoing major changes, the following minor policy changes were made.

Provisions relating to destruction or other disposition of records were dropped from § 2.21 (§ 2.22 in the May 9 proposal) as unnecessary except in the case of programs discontinuing operations.

The fixed limitation on the permissible duration of written consent for disclosure was dropped from § 2.31 in favor of a limitation to such duration as may be reasonably necessary to effectuate the purpose for which the consent is given.

The specification of crimes in § 2.65 for which a court order may be granted authorizing use of program records in the investigation or prosecution of a patient was broadened to cover any "extremely serious" crime, with those listed in the May 9 notice being retained as examples.

Finally, a number of clarifying, technical, and conforming changes were made in the May 9 proposal, but these are without significant substantive effect.

Accordingly, pursuant to the authority of section 408 of the Drug Abuse Office and Treatment Act of 1972, as amended by Pub. L. 92–282 (21 U.S.C. 1175), and section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, as amended by Pub. L. 93–282 (42 U.S.C. 4582), and under the authority delegated to the General Counsel of the Special Action Office for Drug Abuse Prevention (39 FR 17901, May 21, 1974), Subchapter A of Chapter I, Title 42, Code of Federal Regulations, is amended by inserting immediately after Part 1 thereof a new Part 2 to read as set forth below.

Effective date. These regulations shall be effective on August 1, 1975.

Dated: June 25, 1975.

R. MOURE,
Acting Assistant Secretary for Health, Department of Health, Education, and Welfare.

Approved: June 26, 1975.

CASPAR W. WEINBERGER,
Secretary of Health, Education, and Welfare.

Dated: June 27, 1975.

GRASTY CREWS II,
General Counsel, Special Action Office for Drug Abuse Prevention.

Dated: June 27, 1975.

ROBERT L. DUPONT,
Director, Special Action Office for Drug Abuse Prevention.

Subpart A—Introductory Statement

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2.1 Statutory authority—drug abuse.
2.2 Statutory authority—alcohol abuse.
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2.4 General purposes.
2.5 Format.
2.6 Administration and enforcement in general.
2.7 Reports of violations.

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2.11–1 Definitions and usages—basis and purpose.
2.12 Applicability—rules.
2.12–1 Applicability—basis and purpose.
2.13 General rules regarding confidentiality—rules.
2.13–1 General rules regarding confidentiality—basis and purpose.
2.14 Penalty for violations—rules.
2.14–1 Penalty for violations—basis and purpose.
2.15 Minor patients—rules
2.15–1 Minor patients—basis and purpose.
2.16 Incompetent and deceased patients—rules.
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2.20 Identification cards—rules.
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2.21 Disposition of discontinued program records—rules.
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2.22 Former employees and others—rules.
2.22–1 Former employees and others—basis and purpose.
2.23 Relationship to State laws—rules.
2.23–1 Relationship to State laws—basis and purpose.
2.24 Relationship to section 303(a) of Public Health Service Act and section 502(c) of Controlled Substances Act—rules.
2.24–1 Relationship to section 303(a) of Public Health Service Act and section 502(c) of Controlled Substances Act—basis and purpose.

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2.33 Diagnosis, treatment, and rehabilitation—rules.
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2.34 Prevention of certain multiple enrollments—rules.
2.34–1 Prevention of certain multiple enrollments—basis and purpose.
2.35 Legal counsel for patient—rules.
2.35–1 Legal counsel for patient—basis and purpose.
2.36 Patient's family and others—rules.
2.36–1 Patient's family and others—basis and purpose.
2.37 Third party payers and funding sources—rules.
2.37–1 Third party payers and funding sources—basis and purpose.

Sec.
2.38 Employers and employment agencies—rules.
2.38-1 Employers and employment agencies—basis and purpose.
2.39 Criminal justice system referrals and functions—rules.
2.39-1 Criminal justice system referrals and functions—basis and purpose.
2.40 Situations not otherwise provided for—rules.
2.40-1 Situations not otherwise provided for—basis and purpose.

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2.51 Medical emergencies—rules.
2.51-1 Medical emergencies—basis and purpose.
2.52 Research, audit, and evaluation—rules.
2.52-1 Research, audit, and evaluation—basis and purpose.
2.53 Government agencies—rules.
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2.54 Patient identifying information in connection with examinations—rules.
2.54-1 Patient identifying information in connection with examinations—basis and purpose.
2.55 Supervision and regulation of narcotic maintenance and detoxification programs—rules.
2.55-1 Supervision and regulation of narcotic maintenance and detoxification programs—basis and purpose.
2.56 Prohibition on disclosure of patient identities from research, audit, or evaluation records—rules.
2.56-1 Prohibition on disclosure of patient identites from research, audit, or evaluation records—basis and purpose.

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2.62 Inapplicability to secondary records—rules.
2.62-1 Inapplicability to secondary records—basis and purpose.
2.63 Limitation to objective data—rules.
2.63-1 Limitation to objective data—basis and purpose.
2.64 Procedures and criteria in general—rules.
2.64-1 Procedures and criteria in general—basis and purpose.
2.65 Investigation and prosecution of patients—rules.
2.65-1 Investigation and prosecution of patients—basis and purpose.
2.66 Investigation and prosecution of programs—rules.
2.66-1 Investigation and prosecution of programs—basis and purpose.
2.67 Undercover agents and informants—rules.
2.67-1 Undercover agents and informants—basis and purpose.

Subpart A—Introductory Statement

§ 2.1 Statutory authority—drug abuse.

(a) *Statutory provisions effective May 14, 1974.* Insofar as the provisions of this part pertain to any program or activity relating to drug abuse education, training, treatment, rehabilitation, or research, such provisions are authorized under section 408 of Pub. L. 92-255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) as amended by section 303 of Pub. L. 93-282 (88 Stat. 137). That section reads as follows:

§ 408. Confidentiality of patient records.

(a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (c), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b)(1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) The Director of the Special Action Office for Drug Abuse Prevention, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Director are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(b) *Amendments effective June 30, 1975.* Effective on the date specified in section 104 of the Drug Abuse Office and Treatment Act of 1972 (June 30, 1975), the first sentence of section 408(g) above, will be amended by striking "Director of the Special Action Office for Drug Abuse Prevention" and inserting in lieu thereof "Secretary of Health, Education, and Welfare", and the second sentence of such section will be amended by striking "Director" and inserting "Secretary" in lieu thereof. Also effective on that date, section 408, above, will be further amended by (1) striking out "The" and inserting in lieu thereof "Except as provided in subsection (h) of this section, the" in the first sentence of subsection (g) of such section; and (2) adding at the end of such section the following new subsection:

(h) The Administrator of Veterans' Affairs, through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations established by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from drug abuse. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall, from time to time, consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

§ 2.2 Statutory authority—alcohol abuse.

Insofar as the provisions of this part pertain to any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, such provisions are authorized under section 333 of Pub. L. 91-616, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. 4582), as amended by section 122(a) of Pub. L. 93-282, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974 (88 Stat. 131). As so amended, that section reads as follows:

CONFIDENTIALITY OF RECORDS

SEC. 333. (a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b)(1) The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g).

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) The Administrator of Veterans' Affairs, through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from alcohol abuse or alcoholism. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall, from time to time, consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

§ 2.3 Previous regulations as controlling authority.

Attention is called to the interpretative regulations, issued by the Special Action Office for Drug Abuse Prevention (37 FR 24636, November 17, 1972, as revised 38 FR 33744, December 6, 1973, referred to hereinafter in this part as the "previous regulations"). Those regulations have been given a special status as controlling authority by the provisions of section 303(d) of Pub. L. 93-282, as well as the references in the legislative history of that act to the precedents established under section 408 of Pub. L. 92-255. Such references appear at page 11 of House Committee Report No. 93-759 and at page H3563 of the Congressional Record for May 6, 1974. The latter citation is to a detailed analysis of the bill in its final form which was submitted for the Record by its floor manager, Chairman Staggers of the Interstate and Foreign Commerce Committee, when the bill was up for final action by the House of Representatives.

§ 2.4 General purposes.

(a) *Policy objectives.* The purpose of the regulations set forth in this part is to implement the authorizing legislation in a manner that, to the extent practicable, takes into account two streams of legal thought and social policy. One has to do with enhancing the quality and attractiveness of treatment systems. The other is concerned with the interests of patients as citizens, most particularly in regard to protecting their rights of privacy. Within each stream there are cross-currents, and it should come as no surprise that areas of turbulence are to be found at their confluence.

(b) *Limited purpose.* The regulations contained in this part are not intended to direct the manner in which substantive functions, such as research, treatment, and evaluation, should be carried out, but rather to define the minimum requirements for the protection of confidentiality of patient records which must be satisfied in connection with the conduct of those functions in order to carry out the purposes of the authorizing legislation. This does not mean that observance of only the minimum legal requirements is always the wisest course, but in framing these regulations, allowance has necessarily been made for a diversity of emphasis and approach in the many different jurisdictions and by the great variety of public and private agencies which must find a way to function within the limits here prescribed.

§ 2.5 Format.

(a) *Basis and purpose sections.* Each section setting forth rules on any given topic in Subparts B through E of this part is followed by a section setting forth their basis and purpose. In many cases, the basis and purpose section is itself an interpretative rule regarding the legal authority of the rulemakers. In other instances, it summarizes historical or evidentiary material relevant to the validity and interpretation of the section which precedes it.

(b) *Statutory rules fully incorporated.* Although, for convenience of reference, the statutory basis for this part is set out in full in §§ 2.1 and 2.2, the regulations in Subparts B through E of this part are intended to include all of the operative statutory provisions.

§ 2.6 Administration and enforcement in general.

It is not contemplated that any particular agency will be set up specifically to enforce compliance with this part. Programs which receive Federal grants may be monitored for compliance with this and other applicable Federal law as an incident to the grant administration process. Similarly, FDA inspections of methadone programs will include inspection for compliance with this part, which is incorporated by reference in the methadone regulation (21 CFR 310.505).

§ 2.7 Reports of violations.

Any violation may be reported to the United States Attorney for the judicial district in which the violation occurs. Violations on the part of methadone programs may be reported to the regional offices of the Food and Drug Administration. Violations on the part of a Federal grantee or contractor may be reported to the Federal agency monitoring the grant or contract.

Subpart B—General Provisions

§ 2.11 Definitions and usages.—Rules.

(a) *Authorizing legislation.* The term "authorizing legislation" means section 408 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) and section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582), as such sections may be amended and in effect from time to time.

(b) *Construction of terms.* The definitions and rules of construction set forth in this section are applicable for the purposes of this part. To the extent that they refer to terms used in the authorizing legislation, they are also applicable for the purposes of such legislation.

(c) *Alcohol abuse.* The term "alcohol abuse" includes alcoholism.

(d) *Drug abuse.* The term "drug abuse" includes drug addiction.

(e) *Diagnosis and treatment.* The terms "diagnosis" and "treatment" include interviewing, counselling, and any other services or activities carried on for the purpose of or as an incident to diagnosis, treatment, or rehabilitation with respect to drug abuse or alcohol abuse, whether or not conducted by a member of the medical profession.

(f) *Program.*

(1) The term "program", when referring to an individual or organization, means either an individual or an organization furnishing diagnosis, treatment, or referral for alcohol abuse or drug abuse.

(2) The term "program", when not used in the sense defined in paragraph (f)(1), means a plan or procedure, whether functional or organizational, and whether or not governmental, for dealing with alcohol abuse or drug abuse problems from either an individual or a social standpoint.

(g) *Program evaluation.*

The term "program evaluation" means an evaluation of—

(1) The effectiveness, efficiency, compliance with applicable therapeutic, legal, or other standards, or other aspects of the performance, of a program as defined in paragraph (f)(1) of this section, or

(2) The validity, effectiveness, efficiency, practicability, or other aspects of the utility or success of a program in the sense defined in paragraph (f)(2) of this section.

(h) *Program director.* The term "program director" in the case of a program which is an individual means that individual, and in the case of a program which is an organization, the individual, if any, who is the principal, or, in the case of organizations consisting of partners or under the control of a board of directors, board of trustees or other governing body, the individual designated as program director, managing director, or otherwise vested with executive authority with respect to the organization.

(i) *Patient.* The term "patient" means any individual (whether referred to as a patient, client, or otherwise) who has applied for or been given diagnosis or treatment for drug abuse or alcohol abuse and includes any individual who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug or alcohol abuse preliminary to a determination as to eligibility to participate in a treatment or rehabilitation program.

(j) *Patient identifying information.* The term "patient identifying information" means the name, address, social security number, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a patient identifying number assigned by a program.

(k) *Alcohol abuse or drug abuse prevention function.* The term "alcohol abuse or drug abuse prevention function" means any program or activity relating to alcohol abuse or drug abuse education, training, treatment, rehabilitation, or research, and includes any such function even when performed by an organization whose primary mission is in the field of law enforcement or is unrelated to alcohol or drugs.

(l) The term "person" means an individual, a partnership, a corporation, a trust, a Federal or State governmental agency, or any other legally cognizable entity.

(m) *Service organization.* The term "service organization" means a person which provides services to a program such as data processing, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services.

(n) *Qualified service organization.* The term "qualified service organization" means a service organization which has entered into a written agreement with a program pursuant to which the service organization—

(1) acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the program about patients in the program, it is fully bound by the provisions of this part;

(2) undertakes to institute appropriate procedures for safeguarding such information, with particular reference to patient identifying information; and

(3) undertakes to resist in judicial proceedings any efforts to obtain access to information pertaining to patients otherwise than as expressly provided for in this part.

(o) *Records.* The term "records" includes any information, whether recorded or not, relating to a patient, received or acquired in connection with the performance of any alcohol abuse or drug abuse prevention function, whether such receipt or acquisition is by a program, a qualified service organization, or any other person.

(p) *Communications not constituting disclosure.* The following types of communications do not constitute disclosures of records:

(1) Communications of information within a program between or among personnel having a need for such information in connection with their duties.

(2) Communications between a program and a qualified service organization of information needed by the organization to perform its services to the program.

(3) Communications of information which includes neither patient identifying information nor identifying numbers assigned by the program to patients.

(q) *Previous regulations.* The term "previous regulations" refers to the interpretative regulations issued by the Special Action Office for Drug Abuse Prevention, originally published November 17, 1972, 37 FR 24636, as revised December 6, 1973, 38 FR 33744.

(r) *State law.* The term "State law" refers to the law of a State or other jurisdiction, such as the District of Columbia, as distinguished from Federal law in general. As applied to transactions which do not take place in any State or other similar jurisdiction, the term refers to Federal common law as modified by any applicable Federal statutes and regulations.

(s) *Third party payer.* The term "third party payer" means any organization (or person acting as agent or trustee for an organization or fund) which pays or agrees to pay for diagnosis or treatment furnished or to be furnished to a particular individual, where such payment or agreement to pay is on the basis of an individual relationship between the payer and the patient (or a member of the patient's family in the case of self-and-family insurance coverage or similar arrangements) evidenced by a contract, an insurance policy, a certificate of membership or participation, or similar documentation.

(t) *Funding source.* The term "funding source" means any individual or any public or private organization, including any Federal, State, or local governmental agency, which makes payments in support of a program. A funding source is not, as such, a third party payer, even where its payment sare based directly or indirectly on the program's patient load with or without respect to specified categories of eligible persons.

(u) *August 22, 1974 draft.* References to the "August 22, 1974 draft" are to the draft regulations set out in the Advance Notice of Proposed Joint Rulemaking published in the FEDERAL REGISTER on August 22, 1974, 39 FR 30426, by the Department of Health, Education, and Welfare and the Special Action Office for Drug Abuse Prevention.

§ 2.11–1 Definitions and usages.—Basis and purpose.

(a) *In general.* The definitions are based upon the legislative history of and experience with the authorizing legislation, and are intended as aids to construing the provisions of this part to carry out the purposes of those statutes.

(b) *Coverage of applicants for treatment.* Section 2.11(i) is intended to make it clear that records of the identity and other information about a person whose application is rejected or withdrawn are fully as much covered by this part as records pertaining to a patient actually accepted for treatment.

(c) *Program terminology for patients not controlling.* While many programs prefer to use "client" or some other term instead of "patient" to describe the recipients of their services, it is believed preferable to use terminology in this part which is consistent with that used in the authorizing legislation. It should be clearly understood, however, that the records of any individual who fits the definition set forth in § 2.11(i) are covered, no matter what terminology the program may use to designate his status.

(d) *Origin of "prevention function" terminology.* The definition of alcohol abuse or drug abuse prevention function in § 2.11(k) is adapted from the definition of drug abuse prevention function in section 103(b) of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1103(b)). Although there was no corresponding defined term available to the draftsman of the 1974 amendment to section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582), it is clear from the legislative history that the coverage of alcohol abuse patient records was intended to be fully as wide as the coverage of drug abuse patient records, and the definition in § 2.11(k) reflects that intention.

(e) *Ambiguity of the term "program".* It is recognized that it is ordinarily poor drafting technique to use the same term in senses which are as different, yet related, as those in §§ 2.11(f)(1) and 2.11(f)(2). This part, however, has to be read both in conjunction with the Food and Drug Administration's Methadone Regulation and the Drug Abuse Office and Treatment Act of 1972. The Methadone Regulation (21 CFR 310.505) clearly uses the term "program" in the § 2.11(f)(1) sense. In section 103(b) of the Act (21 U.S.C. 1103(b)), it is clearly used in the § 2.11(f)(2) sense, and the usage in section 408(b)(2)(B) of the Act has from its original enactment been administratively interpreted to include both senses. As used in this part, the context should indicate the intended meanings with sufficient clarity to make this preferable to creating and defining new terminology which would be different from that used in related regulations and the authorizing legislation.

(f) *Construction of disclosures.* Section 2.11(p) is intended to clarify the status of communications which are carried on within a program or between a program and persons or organizations which are assisting it in providing patient care. The authorizing legislation was not intended to prohibit programs from carrying on accepted practices in terms of obtaining specialized services from outside organizations. In conjunction with the definition of qualified service organizations, set forth in § 2.11(n), the provisions of § 2.11(p) should prevent the development of abuses in this area.

§ 2.12 Applicability.—Rules.

(a) *In general.* Except as provided in paragraph (b) of this section, this part applies to records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any alcohol abuse or drug abuse prevention function—

(1) Which is conducted in whole or in part, whether directly or by grant, contract, or otherwise, by any department or agency of the United States,

(2) For the lawful conduct of which in whole or part any license, registration, application, or other authorization is required to be granted or approved by any department or agency of the United States,

(3) Which is assisted by funds supplied by any department or agency of the United States, whether directly through a grant, contract, or otherwise, or indirectly by funds supplied to a State or local government unit through the medium of contracts, grants of any description, general or special revenue sharing, or otherwise, or

(4) Which is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program conducting such function, or by a way of a tax-exempt status for such program.

(b) *Armed Forces and Veterans' Administration.*

(1) The provisions of this part do not apply to any interchange, entirely within the Armed Forces, within those components of the Veterans' Administration furnishing health care to veterans, or between such components and the Armed Forces, of records pertaining to a person relating to a period when such person is or was subject to the Uniform Code of Military Justice.

(2) Except as provided in paragraph (b)(1) of this section, this part applies to any communication between any person outside the Armed Forces and any person within the Armed Forces.

(3) Except as provided in paragraph (b)(1) of this section, this part applies, insofar as it pertains to any drug abuse prevention function, to any communication between any person outside those components of the Veterans' Administration furnishing health care to veterans and any person within such components, until such date as the Secretary of Health, Education and Welfare exercises his authority (conferred by an amendment effective June 30, 1975) to prescribe regulations under section 408 of Pub. L. 92–255 (21 U.S.C. 1175). After such date, this part applies thereto to such extent as the Administrator of Veterans' Affairs, through the Chief Medical Director, by regulation makes the provisions of this part applicable thereto.

(4) Except as provided in paragraph (b)(1) of this section, this part applies, insofar as it pertains to any alcohol abuse prevention function, to any communication between any person outside those components of the Veterans' Administration furnishing health care to veterans and any person within such components, to such extent as the Administrator of Veterans' Affairs, through the Chief Medical Director, by regulation makes the provisions of this part applicable thereto.

(c) *Period covered as affecting applicability.* The provisions of this part apply to records of identity, diagnosis, prognosis, or treatment pertaining to any given individual maintained over any period of time which, irrespective of when it begins, does not end before March 21, 1972, in the case of diagnosis or treatment for drug abuse or before May 14, 1974, in the case of diagnosis or treatment for alcohol abuse.

(d) *Applicability determined by nature and purpose of records.* The applicability of the provisions of this part is determined by the nature and purpose of the records in question, and not by the status or primary functional capacity of the recordkeeper.

§ 2.12–1 Applicability.—Basis and purpose.

(a) The broad coverage provided by § 2.12(a) is appropriate in the light of the remedial purposes of the statutes as well as the practical desirability of certainty and uniformity. Sections 2.12(a)(1) and 2.12(a)(2) simply follow the terms of subsection (a) of the statutes, with some explanatory material for the sake of clarity and explicitness.

(b) Sections 2.12(a)(3) and 2.12(a)(4) are based upon the use by Congress of the phrase "directly or indirectly assisted by any department or agency of the United States". In the light of the multiplicity and extent of Federal programs and policies which can be of assistance to drug and alcoholism programs, this wording strongly suggests an intention to provide the broadest coverage consistent with the literal terms of the statutes. Many programs commence with direct Federal assistance, financial, technical, or both, and later continue with State aid and private, tax-deductible contributions. It would be manifestly contrary to the general policy sought to be effectuated by the legislation if the confidential status of a program's records were to terminate, or even be called into question, by the cessation of direct Federal assistance.

(c) With regard to § 212(a)(3), it seems clear that whenever a State or local government is assisted by the Federal government by way of revenue sharing or other unrestricted grants, all of the programs and activities of the State or local government are thereby indirectly assisted, and thus meet that aspect of the statutory criteria for coverage.

(d) Section 2.12(a)(4) follows the doctrine established in *McGlotten v. Connally*, 338 F. Supp. 448 (D.C. D.C., 1972), in which it was held that the deductible status of contributions to an organization constitutes "Federal financial assistance" within the meaning of section 601 of the 1964 Civil Rights Act (42 U.S.C. 2000d). The inclusion of the adjective "indirect" as a modifier of the term "assistance" as used in the provisions of law authorizing this part suggests an intention to provide coverage at least as broad, if not broader than, section 601 of the Civil Rights Act in respect of financial assistance. See, also, *Green v. Connally*, 330 F. Supp. 1150 (D.C. D.C., 1971) aff'd sub. nom. *Coit v Green*, 404 U.S. 997, 92 S. Ct. 564, 30 L. Ed. 2d 550 (1971).

(e) Section 2.12(b) essentially repeats the interpretation given in § 1401.02(b) of the previous regulation except that it takes account of the special provisions inserted in the new law with reference to the Veterans Administration, and makes clear that the exemption for communications within the military-VA system does not generally apply to records pertaining to civilians.

(f) Section 2.12(c), which deals with the question of how the period covered by any given set of records affects the applicability of these regulations to them, restates the principle set forth in § 1401.02(a) of the previous regulations, and applies it to records in the field of alcohol abuse as well as drug abuse. The authorizing legislation contains no effective date provisions. A construction which would apply the statutes to records of completely closed treatment episodes, records necessarily made and maintained prior to the enactment of the legislation, would create serious administrative problems. It seems doubtful, in any case, whether such records have been "maintained," within the meaning of the statutes, during any period of time after their enactment. On the other hand, if treatment is actually carried on after the enactment of the applicable statute, then all the records should be covered irrespective of when treatment was begun, because such records clearly are being "maintained" after the enactment of the legislation.

(g) Section 2.12(d) has been included to make explicit one of the legal implications of the authorizing legislation, which is cast in terms descriptive of the records which are to be confidential rather than of the recordkeepers on whom a duty is thus imposed. The result is that, for example, where a State agency maintains an individual client record which contains identifying information about a client (i.e., patient) receiving treatment or rehabilitation services for drug abuse, such a record is clearly a record maintained in connection with a drug abuse prevention function, and is subject to the provisions of this part. The fact that the record may also be required by statute or regulations pertaining to eligibility for Federal Financial Participation would in no way exempt the record from the prohibitions and requirements of this part. Thus, it would be unlawful and a violation of these regulations for such a record to be made available to a law enforcement agency, or to determine (without the prior written consent of the client) eligibility for other welfare benefits, or for any other administrative or investigative uses or purposes which would involve or result in an identification of the client to a third party.

§ 2.13 General rules regarding confidentiality.—Rules.

(a) *In general.* Records to which this part applies shall be confidential and may be disclosed only as authorized by this part, and may not otherwise be divulged in any civil, criminal, administrative, or legislative proceeding conducted by any Federal, State, or local authority, whether such proceeding is commenced before or after the effective date of this part.

(b) *Unconditional compliance required.* The prohibition upon unauthorized disclosure applies irrespective of whether the person seeking disclosure already has the information sought, has other means of obtaining it, enjoys official status, has obtained a subpoena, or asserts any other justification or basis for disclosure not expressly authorized under this part.

(c) *Information covered by prohibition.* The prohibition on unauthorized disclosure covers all information about patients, including their attendance or absence, physical whereabouts, or status as patients, whether or not recorded, in the possession of program personnel, except as provided in paragraph (d) of this section.

(d) *Crimes on program premises or against program personnel.* Where a patient commits or threatens to commit a crime on the premises of the program or against personnel of the program, nothing in this part shall be construed as prohibiting personnel of the program from seeking the assistance of, or reporting such crime to, a law enforcement agency, but such report shall not identify the suspect as a patient. In any such situation, immediate consideration should be given to seeking an order under Subpart E of this part to permit the disclosure of such limited information about the patient as may be necessary under the circumstances.

(e) *Implicit and negative disclosures prohibited.* The disclosure that a person (whether actual or fictitious) answering to a particular description, name, or other identification is not or has not been attending a program, whether over a period of time or on a particular occasion, is fully as much subject to the prohibitions and conditions of this part as a disclosure that such a person is or has been attending such a program. Any improper or unauthorized request for any disclosure of records or information subject to this part must be met by a noncommittal response.

(f) *In-patients and residents.* The presence of any in-patient in a medical facility or resident in a residential facility for the treatment of drug or alcohol abuse may be acknowledged to callers and visitors with his written consent. Without such consent, the presence of any in-patient or resident in a facility for the treatment of a variety of conditions may be acknowledged if done in such a way as not to indicate that the patient is being treated for drug or alcohol abuse.

§ 2.13–1 General rules regarding confidentiality.—Basis and purpose.

(a) Section 2.13(a) enunciates the general principle of the statutory provisions, and is unchanged from § 1401.03 of the previous regulations.

(b) Sections 2.13(b) and 2.13(c) have been added on the basis of written comments on the draft regulations published August 22, 1974, in which there was a documented report that counsel for a program had advised the program that it could furnish information to the FBI about patients without their written consent and without completing a full judicial proceeding in accordance with Subpart E of this part. Sections 2.13(b) and 2.13(c) should clarify the original intent of the statutes and regulations to the extent of precluding such errors in the future.

(c) In the situation described in § 2.13(d), the desirability of the general prophylactic rule prohibiting disclosures by program personnel about patients regardless of whether such disclosures are from a written record must yield to the practical necessity to permit protection from, and prompt reporting of, criminal acts. In the preface to the first set of regulations issued under 21 U.S.C. 1175, it was emphasized that the operation of that section "in no way creates a sanctuary for criminals." (37 FR 24636, November 17, 1972). Section 2.13(d) is consistent with that contemporaneous administrative construction.

(d) Section 2.13(e) is adapted from § 1401.11 of the August 22, 1974 draft. The suggestion that this part be cited when declining to give information has been deleted on the basis of comments that correctly pointed out that such a citation, if given by an institution or program maintaining some records covered by this part and some not, would serve to identify the records inquired about as pertaining to treatment covered by this part.

Section 2.13(f) merely clarifies the effect of the preceding paragraphs in the special situations to which paragraph (f) relates.

§ 2.14 Penalty for violations.—Rules.

(a) *Penalty provided by law.* Any person who violates any provision of the authorizing legislation or any provision of this part shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(b) *Application to subsequent offenses.* Where a defendant has committed one offense under either section authorizing this part or any provision of this part authorized by that section, any offense thereafter committed under the same section or any provision of this part authorized under that section shall be treated as a subsequent offense.

§ 2.14–1 Penalty for violations.—Basis and purpose.

(a) Section 2.14 states the criminal penalty provided for in subsection (f) of the sections authorizing this part. It is included in this part for convenience and completeness. Some of the comments received on this section when originally proposed suggested that criminal penalties for violation should include imprisonment, but such a change would have to be made by legislation rather than rulemaking.

(b) Section 2.14(b) clarifies the intention that the "subsequent offense" need not be identical to the first offense, as long as it is committed with respect to the same statutory section. For example, a person whose first offense had consisted of improperly releasing the name of a patient in an alcoholism treatment program would be punishable for a "subsequent offense" if he later gives out information from the diagnostic work-up of an alcoholism patient.

§ 2.15 Minor patients.—Rules.

(a) *Definition of minor.* The term "minor" means a person who has not attained the age of 18 years or, in a State where a different age is expressly provided by State law as the age at which a person ceases to be a minor, the age prescribed by the law of such State.

(b) *Consent to disclosure in general.* Except as provided in paragraph (c), where consent is required for any disclosure under this part, such consent in the case of a minor must be given by both the minor and his parent, guardian, or other person authorized under State law to act in his behalf, but any disclosure made after the patient has ceased to be a minor may be consented to only by the patient.

(c) *Rule when State law authorizes treatment without parental consent.* Whenever a patient, acting alone, has the legal capacity under the applicable State law to apply for and obtain such diagnosis, counselling, administration of medication, or other services as actually are or were provided to him by the program with respect to which he is or was a patient, any consent required for disclosure under this part may be given only by the patient, notwithstanding the fact that the patient may be a minor.

(d) *Initial contacts.* When a minor applies for services under circumstances other than those described in paragraph (c) of this section, the fact of such application may not be disclosed, except as an incident to a communication authorized under paragraph (f) of this section, without consent of the applicant, to the applicant's parent, guardian, or other person authorized under State law to act on behalf of the applicant. When such an applicant refuses consent, it must be explained to the applicant that while he or she has the right (subject to the provisions of paragraph (f) of this section) to withhold such consent, the services applied for cannot be provided without it.

(e) *Collection or attempted collection of payment for services.* Where State law authorizes the furnishing of services to a minor without the consent of the minor's parent or guardian, no inquiry may be made of the parent's or guardian's financial responsibility, and no bill, statement, request for payment, or any other communication in respect of such services may be transmitted directly or indirectly to such parent or guardian, without the express written consent of the patient. Such consent may not be made a condition of the furnishing of services except in the case of a program which is not required by law, and does not in fact hold itself out as willing, to furnish services irrespective of ability to pay.

(f) *Applicant lacking capacity for rational choice.* When, in the judgment of a program director a minor applicant for services, because of extreme youth or mental or physical condition, lacks the capacity to make a rational decision on whether to consent to the notification of a parent or guardian, and the situation of the applicant poses a substantial threat to the life or physical well being of the applicant or any other individual, and such threat might be reduced by communicating the relevant facts to a parent or guardian of the applicant, such facts may be so communicated by the program director or by program personnel authorized by the director to do so.

§ 2.15–1 Minor patients.—Basis and purpose.

(a) The statutes authorizing this part are totally silent on the issue of the capacity of a minor to give consent for disclosures, and there is nothing in the legislative history to suggest that the question was ever considered by Congress. The question is, however, one which arises repeatedly, and it is therefore appropriately addressed under the general rulemaking authority conferred by subsection (g) of the authorizing legislation.

(b) Perhaps no legal issues are more highly charged than those affecting the relationship of parent and child. Since Congress has not evidenced an intention to affect this relationship, it is clear that local law should govern, and the task of rulemaking is limited to that of insuring, as far as possible, that the results under Federal law are consistent with local policy.

(c) Where a State has authorized the furnishing of treatment or other services of a given type to a minor without notice to or consent by the parent or guardian, it seems clear that a consistent Federal policy with respect to disclosure requires that consent for any disclosure of the treatment record be given by the minor. This policy, moreover, should not be frustrated by attempts to enforce parental financial responsibility in a situation where the State itself has determined that the minor should have a right to obtain services without involving the parent.

(d) A much more difficult problem is presented in the case of a minor who applies for services in a jurisdiction which has not determined that a minor should have the right to obtain them without parental knowledge or consent. The question may arise as to whether the clinician has an ethical or legal duty to notify the parent which conflicts with a duty of nondisclosure. The rules in § 2.15 are based upon the theory that Federal law should not invalidate a State policy which prohibits treatment without parental consent, but that keeping confidential a mere application for treatment is not ordinarily a sufficient transgression of such a State policy as to require an exception to the general Federal policy prohibiting disclosure of an application for services without the consent of the applicant.

(e) Section 2.15(f) deals with the case of the minor applicant who lacks the capacity to make a rational choice about consenting to disclosure. It is based upon the theory that where a person is actually as well as legally incapable of acting in his own interest, disclosures to a person who is legally responsible for him may be made to the extent that the best interests of the patient clearly so require. Any other rule could subject clinicians to an intolerable choice between violating the provisions of this part on the one hand, or failing to take action to avoid a preventable tragedy involving a minor, on the other. The statutes authorizing this part should not be read as requiring such a choice.

§ 2.16 Incompetent and deceased patients.—Rules.

(a) *Incompetent patients other than minors.* Where consent is required for any disclosure under this part, such consent in the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(b) *Deceased patients.*

(1) *In general.* Except as provided in paragraph (b)(2) of this section, where consent is required for any disclosure of this part, such consent in the case of records of a deceased patient may be given by an executor, administrator, or other personal representative. If there is no appointment of a personal representative, such consent may be given by the patient's spouse, or if none, by any responsible member of the patient's family.

(2) *Vital statistics.* In the case of a deceased patient, disclosures required under Federal or State laws involving the collection of death and other vital statistics may be made without consent.

§ 2.16–1 Incompetent and deceased patients.—Basis and purpose.

Section 2.16 essentially repeats the substance of § 1401.04 of the previous regulations, broadened to reflect the fact that the statutes now allow any consensual disclosures permitted by the regulations, and to cover the situation of deceased patients for whom no formal appointment of an executor, administrator, or other personal representative has been made. Written comments were received to the effect that the power to consent to disclosure in the case of a deceased patient should be limited to a personal representative. The expense of probate or administration in some jurisdictions could cause financial hardship to survivors, and on balance it is believed that where the assets of an estate are insufficient to justify the appointment of a personal representative, the public interest is served by permitting others to consent to disclosure.

§ 2.17 Security precautions.—Rules.

(a) *Precautions required.* Appropriate precautions must be taken for the security of records to which this part applies. Records containing any information pertaining to patients shall be kept in a secure room, or in a locked file cabinet, safe, or other similar container, when not in use.

(b) *Policies and procedures.* Depending upon the type and size of the program, appropriate policies and procedures should be instituted for the further security of records. For example, except where this function is personally performed by the program director, a single member of the program staff should be designated to process inquiries and requests for patient information, and a written procedure should be in effect regulating and controlling access by those members of the staff whose responsibilities require such access, and providing for accountability.

§ 2.17–1 Security precautions.—Basis and purpose.

The enormous variations in both the size and the type of programs to which this part is applicable preclude the formulation of specific requirements with respect to the physical security of records. Almost any requirement which could be laid down would, under some circumstances, either be impracticable or perverse in its effects. For example, in a facility handling a variety of medical records, all of which are confidential and so marked, a requirement that those pertaining to drug or alcohol treatment be marked in any distinctive way would merely serve to identify such records as pertaining to drug or alcohol treatment—precisely the opposite of the intended result. The purpose of § 2.17, which is based upon § 1401.25 of the previous regulations, is to alert programs to the necessity of exercising due care with respect to the security of patient records.

§ 2.18 Extent of disclosure.—Rule.

Any disclosure made under this part, whether with or without the patient's consent, shall be limited to information necessary in the light of the need or purpose for the disclosure.

§ 2.18–1 Extent of disclosure.—Basis and purpose.

(a) Section 2.18 expresses the general principle, which has application in many different contexts, that any disclosure from records covered by this part should be limited to information necessary in the light of the need or purpose for the disclosure. It is identical to § 1401.06 of the previous regulations.

(b) This section should not be misunderstood as imposing a limitation on the scope of records which may or should be made available to health agencies conducting inspections as described in § 2.55. All of the records maintained by a program may be relevant to such inspection. The Congress has determined that disclosure under such circumstances is not a violation of the statutes authorizing this part; where such disclosure is required by Federal or State law, and the inspecting agency is a qualified State health agency as defined in § 2.55(e)(1), it becomes the responsibility of that agency to protect the confidentiality of information it acquires in the course of its lawful activities.

§ 2.19 Undercover agents and informants.—Rules.

(a) *Definitions*. As used in this section, § 2.19–1, and §§ 2.67 and 2.67–1,—

(1) The term "undercover agent" means a member of any Federal, State, or local law enforcement or investigative agency whose identity as such is concealed from either the patients or personnel of a program in which he enrolls or attempts to enroll.

(2) The term "informant" means a person who, at the request of a Federal, State, or local law enforcement or investigative agency or officer, carries on observation of one or more persons enrolled in or employed by a program in which he is enrolled or employed, for the purpose of reporting to such agency or officer information concerning such persons which he obtains as a result of such observation subsequent to such request.

(b) *General prohibition*. Except as otherwise provided in paragraph (c) of this section, or as specifically authorized by a court order granted under § 2.67,—

(1) No undercover agent or informant may be employed by or enrolled in any alcohol or drug abuse treatment program;

(2) No supervisor or other person having authority over an undercover agent may knowingly permit such agent to be or remain employed by or enrolled in any such program; and

(3) No law enforcement or investigative officer may recruit or retain an informant with respect to such a program.

(c) *Exceptions*. The enrollment of a law enforcement officer in a treatment program shall not be deemed a violation of this section if (1) such enrollment is solely for the purpose of enabling the officer to obtain treatment for his own abuse of alcohol or drugs, and (2) his status as a law enforcement officer is known to the program director.

§ 2.19–1 Undercover agents and informants.—Basis and purpose.

(a) In many instances, persons who are patients in treatment programs are making their first tentative efforts toward re-integration into productive society. They may be both vulnerable and suspicious, and the presence in a treatment program of undercover law enforcement agents or informants can have a devastating effect on the program's morale and therapeutic effectiveness. Moreover, it would appear that the purpose of such agents or informants may be to obtain precisely the type of personal information which might be revealed by inspection of counselor notes and other patient records maintained by the program. Thus, the placing of an undercover agent or informant in a program, either as a patient or as an employee, would appear to be contrary to the purposes for which the provisions of law authorizing this part were enacted, and properly subject to prohibition under regulations expressly authorized to carry out those purposes.

(b) From a policy standpoint, § 2.19 is based on the reasoning that while the use of undercover agents and informants in treatment programs is ordinarily to be avoided, there may occasionally arise circumstances where their use may be justified. Accordingly, where a showing is made in an application for an order under § 2.67 that the criteria set forth in that section are satisfied, the court may grant such an order.

(c) When this section of the regulations was proposed, numerous written comments were received urging that there be an absolute prohibition on the use of undercover agents and informants, and most of the witnesses at the hearings who addressed the issue at all testified to the same effect. A number of comments were received to the effect that § 2.19 should be dropped altogether, but this request was always clearly and often explicitly predicated on the assumption that failure to say anything about undercover agents and informants would make their use illegal. Our view is to the contrary; we think that the statutes, standing alone, do not prohibit the practice, and thus that in the absence of a specific prohibition in these regulations, the use of undercover agents and informants in treatment programs would not be unlawful. Since this is a view which we believe to be shared by the law enforcement and investigative agencies which are affected by § 2.19, there is as a practical matter no alternative to predicating these regulations upon its correctness.

(d) However desirable it may be to limit the use of undercover agents and informants in treatment programs, we think a strong argument can be made against our power to impose an absolute prohibition. To the extent that the practice is susceptible to regulation through the rulemaking process at all, it is on the theory that it opens the way to disclosure of information which is or should be in program records, and thus is contrary to the purposes of the statutes. Since subsection (g) of the statutes confers express rulemaking authority to carry out these purposes, regulation of the use of undercover agents and informants is a proper subject for the exercise of that authority. But even the express statutory prohibition against direct disclosure of the content of patient records is subject to the power of the courts to authorize such disclosure under subsection (b)(2)(C) of the statutes. It seems difficult to argue that Congress intended to confer on rulemaking agencies the authority to impose an absolute prohibition even though its own restrictions (other than those on disclosures of patient identities from secondary records) are subject to being set aside by court order in particular cases. Since we have not attempted to exercise such an authority, it is not necessary to decide at this time whether it was conferred

(e) A careful reading of the definitions set forth in § 2.19(a) is crucial to an understanding of the prohibitions which are imposed by § 2.19. Objections to the section were made informally but vigorously on behalf of the Drug Enforcement Administration, on the ground that the testimony of informants or undercover agents is frequently if not normally essential to the successful prosecution of cases arising under the Controlled Substances Act. It was said that in the form originally proposed, the section would cut off from treatment those who might agree to cooperate with law enforcement authorities, a result both inhumane and counterproductive. As the definition of an informant is intended to make clear, however, it is his function vis-a-vis personnel and fellow patients in the program in which he is enrolled which is controlling, and not his relationship, *per se*, with an investigative agency.

(f) Finally, the definition of informant is intended to clarify the distinction between an informant and an ordinary witness. It is the element of prearrangement which is crucial. In one of the comments received on §2.19 as proposed, it was urged that treatment programs should be considered as sanctuaries, but such a result was explicitly disclaimed in the initial publication of the previous regulations (37 FR 24636). In so saying, we are by no means insensitive to the anxieties repeatedly expressed in both testimony and comments on this section, but we believe that the prohibition contained in § 2.19 and the procedures and criteria set forth in § 2.67 provide a measure of relief which is consistent with the structure and intent of the underlying statutes.

§ 2.20 Identification cards.—Rules.

(a) *Required use prohibited*. No program may require or request any patient to carry in his or her possession, while away from the program premises, an identification card or other form of identification which is issued by the program or which would tend to identify the bearer as a participant in it or any similar program.

(b) *Conditions of voluntary use*. Nothing in this section prohibits a program from issuing an identification card to a patient if the patient's counsellor or other authorized member of the program staff has explained to the patient that acceptance and use of the card is entirely voluntary and that neither an initial rejection nor a subsequent discontinuation of its use will in any way prejudice his or her record or standing in the program. In the case of any patient to whom an identification card or similar device was issued prior to the effective date of this section, or subsequent thereto in violation of this section, a counsellor or other authorized member of the program staff shall explain to the patient his right to turn it in without prejudice at any time.

(c) *On-premises exemption*. Nothing in this section prohibits a program from maintaining and using on its premises cards, photographs, tickets, or other devices, or using passwords or other information, to assure positive identification of patients, correct recording of attendance or medication, or for other proper purposes, as long as no pressure is brought on any patient to carry any such device when away from the program premises.

§ 2.20–1 Identification cards.—Basis and purpose.

Section 2.20 is in furtherance of one of the basic purposes of the statutes authorizing this part, namely, protection of patients from improper disclosure of their status as such. Regrettably, there appear to be areas where possession of a treatment program identification card can be prejudicial to a person under arrest or subjected to a search. In any part of the country, the accidental display or circulation of such a card by reason of its loss or theft could have adverse consequences for a variety of reasons. Since programs have other means of achieving the ends which identification cards are meant to serve, patients who do not wish to assume whatever risks may be involved in carrying such cards should not be compelled to do so.

§ 2.21 Disposition of discontinued program records.—Rules.

(a) *General rule*. When a program discontinues operations or is taken over or acquired by another program, its records to which this part applies with respect to any patient may, with the written consent of that patient, be turned over to the acquiring program or, if none, to any other program specified in the patient's consent. Except as otherwise provided in this section, any records to which this part applies, but for the transfer of which patient consent is not obtained, shall be either completely purged of patient identifying information, or destroyed. If any effort to obtain consent for transfer is made, it shall be by means which minimize the likelihood of accidental or incidental disclosure to any third party of the patient's identity as such.

(b) *Retention period*. Where records are required by law to be kept for a specified period, and such period does not expire until after the discontinuation or acquisition of the program, and patient consent for their transfer is not obtained, such records shall be sealed in envelopes or other containers marked or labelled as follows: "Records of [insert name of program] required to be maintained pursuant to [insert citation to law or regulation requiring that records be kept] until a date not later than December 31, [insert appropriate year]." The same procedure may be followed when it is determined to retain records for the period of any applicable statute of limitations.

(c) *Custodial retention*. Records marked and sealed in accordance with paragraph (b) of this section may be held by any lawful custodian, but may be disclosed by such custodian only under such circumstances and to such extent as would be permissible for the program in which they originated. As soon as practicable after the date specified on the label or legend required to be affixed pursuant to paragraph (b) of this section, the custodian shall destroy the records. In the case of any program terminated by reason of bankruptcy, the expense of compliance with this paragraph shall be an expense of administration of the bankrupt estate.

§ 2.21–1 Disposition of discontinued program records.—Basis and purpose.

While arguments can be made for requiring the destruction of records at the conclusion of their useful clinical life, there is wide disagreement on its span, and there are in addition research considerations which argue for an even longer period of retention. Except in the case of discontinued programs, it therefore seems best to leave this issue for determination by the programs concerned.

§ 2.22 Former employees and others.—Rules.

The prohibitions of this part on disclosure of patient records or information contained therein apply to all individuals who are personnel of treatment programs, researchers, auditors, evaluators, service organizations, or others having access to such records or information, and continue to apply to such individuals with respect to such records or information after the termination of their employment or other relationship or activity giving rise to such access.

§ 2.22–1 Former employees and others.—Basis and purpose.

The probition contained in § 2.22 is arguably an interpretation of the authorizing legislation which would be necessary as a matter of law even in the absence of this part; its validity as an exercise of the rulemaking power conferred by subsection (g) of the authorizing legislation seems beyond dispute.

§ 2.23 Relationship to State laws.—Rules.

The enactment of the provisions of law authorizing this part was not intended to preempt the field of law covered thereby to the exclusion of State laws not in conflict therewith. If a disclosure permitted under the provisions of this part, or under a court order issued pursuant thereto, is prohibited under State law, nothing in this part or in the provisions of law authorizing this part may be construed to authorize any violation of such State law. No State law, however, may either authorize or compel any disclosure prohibited by this part.

§ 2.23–1 Relationship to State laws.—Basis and purpose.

Section 2.23 sets forth publicly an interpretation which, in informal communications, has consistently been given to 21 U.S.C. 1175 since its original enactment, and clearly has equal applicability to 42 U.S.C. 4582.

§ 2.24 Relationship to section 303(a) of Public Health Service Act and section 502(c) of Controlled Substances Act.—Rules.

(a) *Research privilege description*. In some instances, there may be concurrent coverage of a program or activity by the provisions of this part and by a regulation or other administrative action under section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)). The latter two provisions of law, referred to hereinafter in this section as the research privilege sections, confer on the Secretary of Health, Education, and Welfare, and on the Attorney General, respectively, the power to authorize researchers to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subject of such research. The Secretary of Health, Education, and Welfare may grant this privilege with respect to any "research on mental health, including research on the use and effect of alcohol and other psychoactive drugs." The Attorney General's power is conferred as part of a section authorizing research related to enforcement of laws under his jurisdiction concerning substances which are or may be subject to control under the Controlled Substances Act, but is not expressly limited to such research. Regardless of whether a grant of research privilege is made by the Secretary or by the Attorney General, it is expressly provided that persons who obtain it "may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify" the subjects of research for which the privilege was obtained.

(b) *Comparison with authority for this part.* Although they deal, in a sense, with the same subject matter, and may on occasion concurrently cover the same transactions, it is important to note the differences between the research privilege sections (21 U.S.C. 872(c) and 42 U.S.C. 242a(a)) and the provisions of law (21 U.S.C. 1175 and 42 U.S.C. 4582) which authorize this part. Briefly, these differences are as follows:

(1) Although they contain broad grants of express rulemaking authority, the provisions of law by which this part is authorized are self-executing in the sense that they are operative irrespective of whether the rulemaking authority is exercised. The protection afforded by the research privilege sections, on the other hand, can only come into existence as a result of affirmative administrative action.

(2) The provisions of law authorizing this part, as well as the provisions of this part itself, impose affirmative duties with respect to the records to which they apply, and the violation of such duties is subject to criminal penalties. To the extent that a privilege is thereby created, it grows out of the duties thus imposed. The research privilege sections, by contrast, impose no duties by their own terms, and if any duties are implied from their existence, they would have to be enforced on the basis of an implicit civil liability for damages or by equitable relief, as there are no criminal or administrative sanctions available.

(3) The exercise of the authority conferred by the research privilege sections is subject to administrative discretion, whereas in the case of the duties imposed under this part there is judicial discretion, within the limits and subject to procedures and criteria prescribed by statute and regulation, to grant relief in particular cases.

(c) *Grant of research privilege not affected by (b)(2)(C) order.* The issuance of an order under subsection (b)(2)(C) of either of the sections authorizing this part (21 U.S.C. 1175 and 42 U.S.C. 4582) in no way affects the continuing effectiveness of any exercise of the authority of the Secretary of Health, Education, and Welfare under 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) or the Attorney General under section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)).

§ 2.24-1 Relationship to section 303(a) of Public Health Service Act and section 502(c) of Controlled Substances Act.—Basis and purpose.

(a) In Pub. L. 93-282, the Congress expressly amended (by sections 122(a) and 303(a), 88 Stat. 131 and 137) the provisions of law which authorize this part, expressly amended (by section 122 (b), 88 Stat. 132) the research privilege section under the Secretary's jurisdiction, and made explicit reference (in section 303(d), 88 Stat. 139) to the regulations previously issued by the Special Action Office for Drug Abuse Prevention reconciling the provisions of section 408 of the Drug Abuse Office and Treatment Act of 1972 with the provisions of the research privilege sections. When the bill which became Pub. L. 93-282 was before the House of Representatives for its last Congressional consideration before transmission to the President, its floor manager, Chairman Staggers of the Committee on Interstate and Foreign Commerce, inserted in the Record a detailed analysis of the bill in its final form (Congressional Record, daily edition, May 6, 1974, page H3563). This analysis contained the following paragraph:

> The relationship of section 303(a) of the Public Health Service Act, authorizing the administrative grant of absolute confidentiality for research, to section 408 of the Drug Abuse Office and Treatment Act of 1972, requiring that Federally-connected drug abuse patient records generally be kept confidential, has been correctly described in an interpretative regulation, 21 C.F.R. 1401.61 and 1401.62, which was upheld in *People v. Newman*, 32 N.Y. 2d 379, [reversing] 336 N.Y.S. 2d 127, 298 N.E. 2d 651 (1973); *certiorari* denied, [414] U.S. [1163], 94 S. Ct. 927, [39 L. Ed. 2d 116] (1974). For that reason, among others, section 303(d) of the Senate amendment expressly continues the effectiveness of the current regulation promulgated by the Director of the Special Action Office for Drug Abuse Prevention. Thus, although section 502(c) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is not explicitly referred to in this legislation, the congressional intent is clear that the authority conferred by that section was not modified by Pub. L. 92-255, and is not intended to be modified by the bill now before the House.

(b) Sections 2.24 and 2.61 restate, in substance, the interpretative rules (§§ 1401.61 and 1401.62 of the previous regulations) referred to in the passage quoted in paragraph (a) of this section, modified to reflect the amendment made to section 303(a) of the Public Health Service Act (42 U.S.C. 242(a)) by Pub. L. 93-282.

Subpart C—Disclosures With Patient's Consent

§ 2.31 Written consent required.—Rules.

(a) *Form of consent.* Except as otherwise provided, a consent for a disclosure under this part must be in writing and must contain the following:

(1) The name of the program which is to make the disclosure.

(2) The name or title of the person or organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose or need for the disclosure.

(5) The extent or nature of information to be disclosed.

(6) A statement that the consent is subject to revocation at any time except to the extent that action has been taken in reliance thereon, and a specification of the date, event, or condition upon which it will expire without express revocation.

(7) The date on which the consent is signed.

(8) The signature of the patient and, when required under § 2.15, the signature of a person authorized to give consent under that section; or, when required under § 2.16, the signature of a person authorized to sign under that section in lieu of the patient.

(b) *Duration of consent.* Any consent given under this subpart shall have a duration no longer than that reasonably necessary to effectuate the purpose for which it is given.

(c) *Disclosure prohibited with deficient consent.* No program may disclose any information on the basis of a consent form—

(1) which on its face substantially fails to conform to any of the requirements set forth in paragraph (a), of this section, or

(2) which is known, or in the exercise of reasonable care should be known, to the responsible personnel of the program to be materially false in respect to any item required to be contained therein pursuant to paragraph (a) of this section.

(d) *Falsification prohibited.* No person may knowingly make, sign, or furnish to a program any consent form which is materially false with respect to any item required to be contained therein pursuant to paragraph (a) of this section.

§ 2.31-1 Written consent required.—Basis and purpose.

(a) The use of a consent form containing all of the elements specified in § 2.31(a) is necessary to assure compliance with the requirements of this subpart. Under § 1401.21 of the previous regulations, a much more abbreviated form was permissible, because the circumstances under which any consent could be given were very strictly limited. Now that the authorizing legislation permits disclosure with consent "to such extent, under such circumstances, and for such purposes as may be allowed under regulations," the consent form should show on its face information sufficient to indicate compliance with the regulations.

(b) Sections 2.31(b), 2.31(c), and 2.31 (d) are an exercise of the general rulemaking authority in subsection (g) of the authorizing legislation. Section 2.31 (c) imposes a legal liability on programs and their personnel for disclosure of information on the basis of a materially deficient consent, and § 2.31(d) imposes liability on any person who submits a falsified consent form to a program.

§ 2.32 Prohibition on redisclosure.—Rules.

(a) *Notice to accompany disclosure.* Whenever a written disclosure is made under authority of this subpart, except a disclosure to a program or other person whose records pertaining to the patient are otherwise subject to this part, the disclosure shall be accompanied by a written statement substantially as follows: "This information has been disclosed to you from records whose confidentiality is protected by Federal law. Federal regulations (42 CFR Part 2) prohibit you from making any further disclosure of it without the specific written consent of the person to whom it pertains, or as otherwise permitted by such regulations. A general authorization for the release of medical or other information is NOT sufficient for this purpose." An oral disclosure may be accompanied or followed by such a notice.

(b) *Consent required for redisclosure.* A person who receives information from patient records and has been notified substantially in accordance with paragraph (a) of this section is prohibited from making any disclosure of such information except with the specific written consent of the person to whom it pertains, or as otherwise permitted under this part.

(c) *Restriction on redisclosure.* Whenever information from patient records is needed by any person, such information must be obtained directly from the program maintaining such records and not from another person to whom disclosure thereof has been made, except where the initial disclosure was intentionally and expressly made for the purpose of redisclosure (as for example in the case of an employment agency), or the information is no longer available from the program and redisclosure is not prohibited by any other provision of this part.

§ 2.32–1 Prohibition on redisclosure.—Basis and purpose.

(a) Section 2.32 is intended to provide a reasonable protection against redisclosure of information disclosed with consent in accordance with this subpart. There is, of course, no problem where the information becomes part of a record which is itself subject to this part because it is maintained in connection with the performance of a covered substance abuse prevention function. The difficulty arises when the disclosure is made to those whose records are not otherwise affected by this part. To attempt to make all of the provisions of this part applicable to such recipients with respect to such information might raise serious problems of legality, administrative feasibility, and fairness, but where they are given actual notice that specific patient consent is normally required for redisclosure, we think they can and should be bound by it.

(b) Oral disclosures are not mandatorily covered because they should rarely be made to any recipient with whom the program does not have a continuing relationship. Where such a relationship exists or the program is otherwise satisfied that the recipient understands and will respect the confidential nature of the information supplied, there seems no need to add to the already heavy load of paperwork with which programs must contend.

§ 2.33 Diagnosis, treatment, and rehabilitation.—Rules.

(a) *Disclosure authorized.* Where consent is given in accordance with § 2.31, disclosure of information subject to this part may be made to medical personnel or to treatment or rehabilitation programs where such disclosure is needed in order to better enable them to furnish services to the patient to whom the information pertains.

(b) *Traveling, incarcerated, or hospitalized patients on medication.* Where a patent on medication is at a distance from his normal residence or treatment program or is incarcerated or hospitalized, or is otherwise unable to deliver a written consent to his treatment program at the time the disclosure is needed, confirmation of the patient's status and information necessary to appropriately continue or modify his medication may be given to medical personnel in a position to provide services to the patient upon the oral representation of such personnel that the patient has requested medication and consented to such disclosure. Any program making a disclosure in accordance with this paragraph shall make a written memorandum showing the name of the patient, or the patient's case number assigned by the program, the date and time the disclosure was made, the information disclosed, and the names of the individuals by whom and to whom it was made.

§ 2.33–1 Diagnosis, treatment, and rehabilitation.—Basis and purpose.

(a) Section 2.33(a) is a restatement of the policy set forth in § 1401.22(a) of the previous regulations, expanded to make explicit reference to nonmedical counselling and other treatment and rehabilitative services.

(b) Section 2.33(b) clarifies the corresponding provision in § 1401.22(a) of the previous regulations by specifying how and through whom oral consent can be given, and limiting the disclosure to that necessary to determine appropriate medication.

§ 2.34 Prevention of certain multiple enrollments.—Rules.

(a) *Definitions.* For the purposes of this section and § 2.55—

(1) The terms "administer", "controlled substance", "dispense", "maintenance treatment", and "detoxification treatment" shall respectively have the meanings defined in paragraphs (2), (6), (10), (27), and (28) of section 102 of the Controlled Substances Act (21 U.S.C. 802).

(2) The term "program" means a program which offers maintenance treatment or detoxification treatment.

(3) The term "permissible central registry" means a qualified service organization which collects or accepts, from two or more programs (referred to hereinafter as member programs) all of which are located either within a given State or not more than 125 miles from the nearest point on the border of such State, patient identifying information about persons applying for maintenance treatment or detoxification treatment for the purpose of enabling the member programs to prevent any individual from being concurrently enrolled in more than one such program.

(b) *Use of central registries prohibited except as expressly authorized.* The furnishing of patient identifying information by a program to any central registry which fails to meet the definition of a permissible central registry set forth in paragraph (a)(3) of this section is prohibited, and the furnishing of patient identifying information to or by any central registry except as authorized in this section is prohibited. Information pertaining to patients held by a central registry may be furnished or used in accordance with paragraphs (e), (f), and (g) for the purpose of preventing multiple enrollments, but may not be otherwise furnished or used in connection with any legal, administrative, supervisory, or other action with respect to any patient.

(c) *Safeguards and procedures required.* To minimize the likelihood of disclosures of information to impostors or others seeking to bring about unauthorized or improper disclosure, any communications carried on by programs pursuant to this section must be conducted (1) by authorized personnel designated in accordance with § 2.17(b), and (2) in conformity with procedures established in accordance with that section.

(d) *Disclosures with respect to patients in treatment.* A member program may supply patient identifying information and information concerning the type of drug used or to be used in treatment and the dosage thereof, with relevant dates, to a permissible central registry with respect to any patient—

(1) When the patient is accepted for treatment,

(2) When the type or dosage of the drug is changed, and

(3) When the treatment is interrupted, resumed, or terminated.

(e) *Disclosures with respect to applications.* When any person applies to a program for maintenance treatment or detoxification treatment, then for the purpose of inquiring whether such person is currently enrolled in another program for such treatment, the program may furnish patient identifying information with respect to such person—

(1) To any permissible central registry of which the program is a member, and

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(2) To any other program which is not more than 200 miles distant and which is not a member of any central registry of which the inquiring program is a member.

(f) *Program procedure in case of apparent concurrent enrollment.* When an inquiry pursuant to paragraph (e)(2) is made of another treatment program and its response is affirmative, the two programs may engage in such further communication as may be necessary to establish whether an error has been made, and if none, the programs should proceed in accordance with sound clinical practice and any applicable regulations pertaining to the type of treatment involved.

(g) *Registry procedure in case of apparent concurrent enrollment.* When an inquiry pursuant to paragraph (e)(1) is made of a permissible central registry and its response is affirmative, it may advise the inquiring program of the name, address, and telephone number of the other program, or it may advise the other program of the identity of the patient and the name, address, and telephone number of the inquiring program, or it may do both, and in any case the two programs may then communicate as provided in paragraph (f) above.

(h) *Advice to patients.* When the policies and procedures of any program involve any disclosures pursuant to this section, before any patient is accepted for or continued in treatment (other than detoxification treatment) after September 30, 1975, written consent in accordance with § 2.31 shall be obtained. Such consent shall set forth a current list of the names and addresses either of any programs or of any central registries to which such disclosures will be made. Notwithstanding the requirement of § 2.31 (a)(2), such consent shall be effective with respect to any other such program thereafter established within 200 miles, or any registry serving such programs, and shall so state. Such consent shall be effective for as long as the patient remains enrolled in the program to which it is given.

§ 2.34–1 Prevention of certain multiple enrollments.—Basis and purpose.

Section 2.34 is based upon § 1401.43 of the previous regulations. It was omitted from the August 22, 1974 draft, but comments on the omission made it clear that in certain areas of the country, central registries are a functional component of the treatment system, and that regulations to guide their operations are needed.

§ 2.35 Legal counsel for patient.—Rules.

When a bona fide attorney-client relationship exists between an attorney-at-law and a patient, disclosure of any information in the patient's records may be made to the attorney upon the written application of the patient endorsed by the attorney. Information so disclosed may not be further disclosed by the attorney.

§ 2.35–1 Legal counsel for patient.—Basis and purpose.

Section 2.35 simplifies and broadens the statement of the policy embodied in § 1401.25 of the previous regulations. Its purpose is to assure the availability to the attorney, with his client's consent, of any information needed as a basis for advice and counsel. The purpose of the prohibition on further disclosure by the attorney is to guard against the possibility that the attorney might be forced to serve as a conduit for otherwise prohibited disclosures to third parties. Ordinarily, the attorney-client privilege would suffice, but that privilege is subject to waiver by the client, whereas this prohibition is not. Where there is a need for disclosure to a third party of any given information about any patient, this prohibition in no way affects the availability of other sections of this part to authorize such disclosure by the program.

§ 2.36 Patient's family and others.—Rule.

Where consent is given in accordance with § 2.31, information evaluating his current or past status in a treatment program may be furnished to any person with whom the patient has a personal relationship unless, in the judgment of the person responsible for the patient's treatment, the disclosure of such information would be harmful to the patient.

§ 2.36–1 Patient's family and others.—Basis and purpose.

Section 2.36 expresses the same policy as was embodied in § 1401.27 of the previous regulations, broadened to reflect the expanded authority for consensual disclosure under the authorizing legislation.

§ 2.37 Third-party payers and funding sources.—Rules.

(a) *Acquisition of information.* Disclosure of patient information to third-party payers or funding sources may be made only with the written consent of the patient given in accordance with § 2.31 and any such disclosure must be limited to that information which is reasonably necessary for the discharge of the legal or contractual obligations of the third-party payer or funding source.

(b) *Prohibition on disclosure.* Where a funding source or third-party payer maintains records of the identity of recipients of treatment or rehabilitation services for alcohol or drug abuse such records are, under the authorizing legislation, maintained in connection with the performance of an alcohol or drug abuse prevention function and are subject to the restrictions upon disclosure set forth in this part.

§ 2.37–1 Third-party payers and funding sources.—Basis and purpose.

Section 2.37 is based upon the general authority to prescribe regulations to carry out the purposes of the authorizing legislation. The great diversity of contractual arrangements and legal requirements under which the operations of third-party payers and funding sources are carried on precludes the prescription of detailed records management instructions in these regulations, even if that were otherwise desirable. The general principles set forth in § 2.37, however, should clarify the question of coverage, and where coverage exists, provide a standard which will minimize the likelihood of violations. See also § 2.12–1(g).

§ 2.38 Employers and employment agencies.—Rules.

(a) *Disclosure permitted.* Where consent is given in accordance with § 2.31, a program may make disclosures in accordance with this section.

(b) *Eligible recipients.* A program may make disclosures under this section to public or private employment agencies, employment services, or employers.

(c) *Scope of disclosure.* Ordinarily, disclosures pursuant to this section should be limited to a verification of the patient's status in treatment or a general evaluation of progress in treatment. More specific information may be furnished where there is a bona fide need for such information to evaluate hazards which the employment may pose to the patient or others, or where such information is otherwise directly relevant to the employment situation.

(d) *Criteria for approval.* A disclosure under this section may be made if, in the judgment of the program director or his authorized representative appointed as provided in § 2.17(b), the following criteria are met:

(1) The program has reason to believe, on the basis of past experience or other credible information (which may in appropriate cases consist of a written statement by the employer), that such information will be used for the purpose of assisting in the rehabilitation of the patient and not for the purpose of identifying the individual as a patient in order to deny him employment or advancement because of his history of drug or alcohol abuse.

(2) The information sought appears to be reasonably necessary in view of the type of employment involved.

§ 2.38–1 Employers and employment agencies.—Basis and purpose.

Section 2.38 is based on the rulemaking power conferred by subsection (b)(1) of the authorizing legislation, and is adapted from § 1401.26 of the previous regulations. Its purpose is to allow disclosures reasonably necessary and appropriate to facilitate the employment of patients and former patients, while protecting patients against unnecessary or excessively broad disclosures. It was urged in a comment received on the August 22, 1974 draft that disclosures to employers be flatly prohibited on the ground that the employer's sole legitimate concern is with on-the-job performance. While we are not unsympathetic to this view, a countervailing consideration is that in the case of an employee or applicant who is known by the employer to have a problem with drugs or alcohol, knowledge by the employer of a genuine effort by the employee to deal with it can make the difference between a job and no job.

§ 2.39 Criminal justice system referrals.—Rules.

(a) *Consent authorized.* Where participation by an individual in a treatment program is made a condition of such individual's release from confinement, the disposition or status of any criminal proceedings against him or the execution or suspension of any sentence imposed upon him, such individual may consent to unrestricted communication between any program in which he is enrolled in fulfillment of such condition and (1) the court granting probation, or other posttrial or pretrial conditional release, (2) the parole board or other authority granting parole, or (3) probation or parole officers responsible for his supervision.

(b) *Duration of consent.* Where consent is given for disclosures described in paragraph (a) of this section, such consent shall expire sixty days after it is given or when there is a substantial change in such person's status, whichever is later. For the purposes of this section, a substantial change occurs in the status of a person who, at the time such consent is given, has been—

(1) Arrested, when such person is formally charged or unconditionally released from arrest;

(2) Formally charged, when the charges have been dismissed with prejudice, or the trial of such person has been commenced;

(3) Brought to a trial which has commenced, when such person has been acquitted or sentenced;

(4) Sentenced, when the sentence has been fully executed.

(c) *Revocation of consent.* An individual whose release from confinement, probation, or parole is conditioned upon his participation in a treatment program may not revoke a consent given by him in accordance with paragraph (a) of this section until there has been a formal and effective termination or revocation of such release from confinement, probation, or parole.

(d) *Restrictions on redisclosure.* Any information directly or indirectly received pursuant to this section may be used by the recipients thereof only in connection with their official duties with respect to the particular individual with respect to whom it was acquired. Such recipients may not make such information available for general investigative purposes, or otherwise use it in unrelated proceedings or make it available for unrelated purposes.

§ 2.39–1 Criminal justice system referrals.—Basis and purpose.

(a) On the basis of extensive written comment and oral communications received on the subject matter of § 2.39 as proposed in the May 9, 1975 notice (designated as § 2.40 in that notice), we have concluded that the latitude allowed and the conditions imposed in § 2.39 as set forth above are necessary and proper to effectuate the purposes of the authorizing legislation.

(b) From a legal standpoint, it seems highly doubtful whether, in a proceeding to revoke probation or parole, the due process requirements laid down in *Morrissey v. Brewer*, 408 U.S. 471, 92 S.Ct. 2593, 33 L.Ed.2d 484 (1972) and *Gagnon v. Scarpelli*, 411 U.S. 778, 93 S.Ct. 1756, 36 L.Ed.2d 636 (1973) could be met by an unsupported general evaluation by a treatment program to the effect that a patient's status or progress in treatment was unsatisfactory. Thus, if such an evaluation were all that could be communicated by a program about a particular patient's conduct during the period he was in treatment, a condition requiring satisfactory participation in a treatment program would to all intents and purposes become unenforceable. Moreover, if it were held to be enforceable, the operative decision on the revocation issue would then be made by the program, arguably exacerbating rather than alleviating its role-conflict problem. It may thus be the part of wisdom to confess that some degree of role-conflict is inherent in the situation of any program which accepts criminal justice referrals. If so, the issue then becomes that of finding the most constructive way to handle the conflict, rather than a sterile and futile effort to avoid it altogether.

(c) We are persuaded that in many instances a prohibition on free communication between probation officers and drug abuse program counsellors would have profoundly deleterious effects on the rehabilitative process. Many probation officers bring to their work a high degree of training, professionalism, and experience. They are under no illusion that they are dealing with a clientelle which will never stumble or relapse, and if they have the information necessary to intervene at an early stage of such an episode, their intervention can often make the difference between success and failure for the client.

(d) There is, however, nothing in these regulations which precludes treatment programs from entering into agreements or arrangements with agencies or institutions of the criminal justice system to regulate or restrict the subject matter or form of communications of information about patients. For example, such an arrangement might provide for free oral communication between counsellors and probation officers, while restricting formal written reports by the program to specified types of so-called hard data such as attendance and urinalysis results. In view of widely differing conditions and attitudes in various parts of the country, substantial variations in such arrangements are not only expectable but desirable.

(e) A further aspect of this matter, which was not adequately considered or dealt with in the May 9 proposal, is the impact which the rules laid down in § 2.39 have on the bail decision. There is a high correlation between the disposition of the application for bail and the type of sentence which may be meted out upon conviction. The contrast between the recidivism rates for those who receive treatment and supervision, as against those who simply receive the punishment of incarceration, is a powerful argument against restrictions which would tend to narrow the circumstances under which conscientious judges can grant bail.

(f) It must be emphasized that § 2.39 in no way reduces the necessity to obtain written consent from patients, whether or not referred by the criminal justice system, before disclosures for the purposes here involved can be made by programs. We have been urged to make an exception from the requirement of § 2.31 in the case of parolees and probationers, but such an exception would be wholly unsupported by the authorizing legislation. In fashioning these regulations, it is not our privilege to adorn a tabula rasa according to our own predilections: rather, it is our duty to interlineate a statute with fidelity to its spirit, its terms, and its purposes.

§ 2.40 Situations not otherwise provided for.—Rules.

(a) *Criteria for approval.* In any situation not otherwise specifically provided for in this subpart, where consent is given in accordance with § 2.31, a program may make a disclosure for the benefit of a patient from the records of that patient if, in the judgment of the program director or his authorized representative appointed as provided in § 2.17, all of the following criteria are met:

(1) There is no suggestion in the written consent or the circumstances surrounding it, as known to the program, that the consent was not given freely, voluntarily, and without coercion.

(2) Granting the request for disclosure will not cause substantial harm to the relationship between the patient and the program or to the program's capacity to provide services in general.

(3) Granting the request for disclosure will not be harmful to the patient.

(b) *Circumstances deemed beneficial.* For the purposes of this section, the circumstances under which disclosure may be deemed to be beneficial to a patient include, but are not limited to, those in which the disclosure may assist the patient in connection with any public or private claim, right, privilege, gratuity, grant or other interest accruing to, or for the benefit of, the patient or the patient's immediate family. Examples of the foregoing include welfare, medicare, unemployment, workmen's compensation, accident or medical insurance, public or private pension or other retirement benefits, and any claim or defense asserted or which is an issue in any civil, criminal, administrative or other proceeding in which the patient is a party or is affected.

§ 2.40–1 Situations not otherwise provided for.—Basis and purpose.

(a) Section 2.40 is based upon § 1401.23 of the previous regulations, amended to reflect the expansion made by the change in the law with respect to the permissible scope of consensual disclosures.

(b) A strong case can be made for the proposition that § 2.40 should, in effect if not expressly, require a program to make any disclosure requested by a patient. The discretion vested in the program, it can be argued, is at best an expression of overprotective paternalism, and at worst, an invitation to programs to cover up material potentially embarrassing to themselves. Bearing in mind, however, that persons who have obtained the type of treatment to which this part applies are more vulnerable to pressures of various kinds than are patients in general, it seems preferable to retain some responsibility on the part of the program to protect the best interests of its patients in this very sensitive area. This, like many other choices which these regulations reflect, is a determination which can be reviewed and revised from time to time in the light of experience.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.—Rules.

(a) *In general.* Disclosure to medical personnel, either private or governmental, is authorized without the consent of the patient when and to the extent necessary to meet a bona fide medical emergency.

(b) *Food and Drug Administration.* Where treatment involves the use of any drug, and appropriate officials of the Food and Drug Administration determine that the life or health of patients may be endangered by an error in the manufacture or packaging of such drug, disclosure of the identities of the recipients of the drug may be made without their consent to appropriate officials of the Food and Drug Administration to enable them to notify the patients or their physicians of the problem in order that corrective action may be taken.

(c) *Incapacitated persons.* Where a patient is incapacitated and information concerning the treatment being given him by a program is necessary to make a sound determination of appropriate emergency treatment, such information may be given without the patient's consent to personnel providing such emergency treatment.

(d) *Notification of family or others.* When any individual suffering from a serious medical condition resulting from drug or alcohol abuse is receiving treatment at a facility which is within the scope of this Part the treating physician may, in his discretion, give notification of such condition to a member of the individual's family or any other person with whom the individual is known to have a responsible personal relationship. Such notification may not be made without such individual's consent at any time such individual is capable of rational communication.

(e) *Record required.* Any program making an oral disclosure under authority of this section shall make a written memorandum showing the patient's name or case number, the date and time the disclosure was made, some indication of the nature of the emergency, the information disclosed, and the names of the individuals by whom and to whom it was disclosed.

§ 2.51–1 Medical emergencies.—Basis and purpose.

The provisions of § 2.51 are adapted from § 1401.42 of the previous regulations, and are based on subsection (b)(2)(A) of the authorizing legislation. The provision in the previous regulations with respect to patients who may be incarcerated is now covered in § 2.33(b).

Paragraph (d) of § 2.51 is based upon the theory that the disclosure there allowed is of the patient's endangered condition, not his identity as a drug or alcohol abuse patient, and that the humanitarian necessity of such notification outweighs its potential for accidental violation of confidentiality

§ 2.52 Research, audit, and evaluation.—Rules.

(a) *Research, audit, and evaluation.* Subject to any applicable specific provision set forth hereinafter in this subpart, the content of records pertaining to any patient which are maintained in connection with the performance of a function subject to this part may be disclosed, whether or not the patient gives consent, to qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner. For the purposes of this subpart and for the purposes of subsection (b)(2)(B) of the authorizing legislation, the term "qualified personnel" means persons whose training and experience are appropriate to the nature and level of the work in which they are engaged and who, when working as part of an organization, are performing such work with adequate administrative safeguards against unauthorized disclosures.

(b) *Use of disclosures of patient identifying information.*

(1) Where a disclosure made to any person pursuant to paragraph (a) of this section includes patient identifying information with respect to any patient, such information may not be further disclosed, and may not be used in connection with any legal, administrative, supervisory, or other action whatsoever with respect to such patient, except as provided in paragraphs (b)(2) and (b)(3) of this section.

(2) The inclusion of patient identifying information in any written or oral communication between a person to whom a disclosure has been made pursuant to paragraph (a) and the program making such disclosure does not constitute the identification of a patient in a report or otherwise in violation of paragraph (a).

(3) Where a disclosure is made pursuant to paragraph (a) of this section to a person qualified to determine, on the basis of such disclosure, the presence of a substantial risk to the health and well being, whether physical or psychological, of any patient, and, in the judgment of such person, such a risk exists and the situation cannot be dealt with solely by means of communications as described in paragraph (b)(2) of this section without intensifying or prolonging the risk as compared with other means of dealing with it, then the initial disclosure under paragraph (a) and any subsequent disclosure or redisclosure of patient identifying information for the purpose of reducing the risk to the patient involved shall be subject to the provisions of § 2.51.

§ 2.52–1 Research, audit, and evaluation.—Basis and purpose.

(a) *General purpose.* Subsection (a) of this section is adapted directly from subsection (b)(2)(B) of the authorizing legislation. The purpose of each is the same: To facilitate the search for truth, whether in the context of scientific investigation, administrative management, or broad issues of public policy, while at the same time safeguarding the personal privacy of the individuals who are the intended beneficiaries of the process or program under investigation. This subpart in particular, and this part as a whole, are intended to aid in carrying out that purpose.

(b) The succeeding sections of this subpart deal with problems which arise in connection with disclosures made for certain specific purposes which have been interpreted as falling within the general purposes embraced by § 2.52. Those sections will be best understood, however, in the light of some discussion of the underlying premises of the general rule, and its relationship to two other legal concepts: the right of privacy, and the duty to obtain informed consent from research subjects.

(c) *The Right of Privacy.* So far as is relevant to this discussion, we may consider the right of privacy in two aspects. One, a protection against improper governmental activity, is the right to be secure against unreasonable searches and seizures guaranteed by the Fourth Amendment, with some expansion from the penumbras of the Fifth and Sixth Amendments. The protections afforded to patients by the authorizing legislation, not to mention these regulations, go far beyond those which are constitutionally required.

(d) The other aspect of the right of privacy, which has sometimes been described as the right to be left alone, is the notion that an individual has a right not to be hurt by intrusions into his essentially personal concerns, or to have essentially private information exploited for commercial gain, whether or not the intrusion or exploitation is in connection with any possible governmental action against him. The courts have spoken of a right of privacy in a wide variety of contexts, but they have repeatedly and explicitly rejected the notion that anyone has a right to go about his daily affairs encapsulated in an impenetrable bubble of anonymity. The courts have been careful to weigh the competing interests, and the social interest in valid research and evaluation is clearly of sufficient moment to be considered in this process.

(e) In defense of the position that disclosure of patient identifying information even for carefully guarded scientific research should be permitted only on a consensual basis, two dominant lines of argument, somewhat interrelated, have emerged. One is that retrospective studies are of questionable value in any case, and the other is that a sampling technique involving informed consent on the part of the members of the sample can always be used to develop the information sought. Neither line of argument will withstand careful scrutiny.

(f) It is true, of course, that the efficacy of a given therapeutic agent can often best be evaluated by means of a well-designed prospective study in which special recordkeeping procedures, special criteria for patient selection, and an appropriate control have all been established with a view to the purpose of the study. There are, however, many important investigations which simply do not lend themselves to such a format. Sometimes the desirability or even the possibility of a particular study does not suggest itself except in retrospect. Another important consideration is the fact that knowledge that an investigation is going on may influence the behavior of patients, clinicians, or both. Where such knowledge can influence the make-up of a sample, it will normally do so in the direction of favorable outcomes, but to an unknown degree, thus tending to invalidate the results reported.

(g) While the sample technique has its uses, especially with populations that are unmanageably large, it is often less difficult and expensive, and less likely to interfere with the actual conduct and outcomes of treatment or rehabilitation processes, to use the full population under study. Even more important than economy and administrative convenience in carrying out a study, there may be an overriding advantage in terms of eliminating any question as to the validity of the results of the study on the ground of bias in the selection of the sample.

(h) *Informed Consent*. The duty to obtain informed consent is obvious and compelling in situations where an individual is exposed to the possibility of harm, either physical or psychological, as a consequence of medical procedures, research, or similar activities. Where such a situation exists the person conducting the research or medical procedure violates his duty to the subject or patient if he proceeds without obtaining the voluntary informed consent from the individual or his legally authorized representative. Thus, in conducting an activity which places the subject or patient at risk the practitioner may not give precedence to a hidden agenda, even for so lofty a motive as the advancement of knowledge. In this regard, see the Department of Health, Education and Welfare's Protection of Human Subjects Regulations, 45 CFR Part 46. Those regulations are applicable to all Department of Health, Education and Welfare grants and contracts supporting research, development and related activities involving human subjects.

(i) It is apparent that the foregoing rationale for requiring informed consent does not apply to the same degree in situations involving the disclosure of clinical records for research in the form of follow-up or retrospective studies. Under these circumstances the risk to the subject is that some disclosure or misuse of information from which he could be identified might result in embarrassment, lost opportunities, or other forms of psychological or social injury. While that possibility of harm could be reduced by requiring consent to every review of clinical records for research purposes, a similar result can be achieved by the less restrictive method of limiting further disclosure of identifying information by the researcher. Given the applicability of this alternative, equally effective means for protecting a patient or subject from the possibility of a harmful public disclosure, it is unreasonable to insist upon informed consent to every review of clinical records for the purposes of conducting legitimate research, particularly since such insistence could lead to the ultimate absurdity of prohibiting efforts to identify the nature and source of an unknown plague simply because the patients or researcher lacked the clairvoyance to have consent forms signed prior to the onset of the affliction.

(j) In sum, there are restraints on certain means of governmental acquisition of information about individuals which are operative irrespective of how the information is used, and there are restraints on the uses of information which are independent of how or by whom it is acquired, but they do not and should not add up to the proposition that the use of information about a person is either morally or legally the absolute prerogative of that person to determine.

(k) For all of these reasons, the authorizing legislation expressly provides that patient consent is not required with respect to disclosures for research, audit, and evaluation, nor does it prohibit individual patient identification in connection with such disclosures. While it is entirely appropriate to impose safeguards and procedures in connection with these activities, it would be wholly inappropriate to use the rulemaking process to impose an absolute requirement of patient consent with respect to activities which by statute may be conducted without it.

(l) *Classification of activities*. It is clear that Congress intended a balancing of the social interest in the validity of the results of inquiry, on the one hand, with the individual interest in anonymity, on the other, all within the limits set by the legislation and the constitution. With that objective in mind, we may now turn to the various categories of activities which come within the purview of this subpart.

(m) These activities may be classified first, in regard to whether participation is voluntary from the standpoint of the program, and second, as to whether the objective is to ascertain compliance with predetermined standards (examinations as defined in § 2.54, and program evaluation as defined in § 2.11(g)(1)), or to ascertain the validity of a given standard or hypothesis (scientific research, and program evaluation as defined in § 2.11(g)(2)). The application of the foregoing classifications logically results in the creation of four categories of activities. Three of them are specifically dealt with in the succeeding sections of this subpart and need not detain us here; the fourth is discussed below.

(n) *Scientific research and evaluation*. Beyond the bare restatement of the authorizing legislation set forth in § 2.52, these regulations are deliberately silent with respect to purely voluntary scientific research and program evaluation in the sense defined in § 2.11(g)(2). Testimony and written comments received on the August 22, 1974 draft regulations were noteworthy in two respects. First, no instances of abuse on the part of persons acquiring patient identifying information under these circumstances were cited. Second, while there was some well-founded criticism of the attempt in that draft to provide guidelines for determining what is scientific research and who is qualified to do it, no usable alternatives—indeed, almost no alternatives at all—were forthcoming.

(o) In one of the written comments, the writer cautioned against any assumption "that our major remaining problems in drug and alcohol abuse treatment are prevention of illicit diversion and protection of confidentiality," and suggested "that we still have a problem in discovering, testing and evaluating improved treatment techniques. To do this," he continued, "one should place minimal obstacles in the way of bona fide clinical and epidemiologic research!"

(p) The result of leaving the rule as it is in the statute, without attempting to sharpen its outlines or define its terms, will be to leave it for interpretation on a case-by-case basis by those who must apply it in practice: the researchers who seek the information, and the programs which supply it. This does not foreclose the possibility of amending the regulations on the basis of experience if it appears either that clinicians are becoming so cautious that research and evaluation studies are being choked off, or that abuses are occurring in the use of information disclosed. But until a need for more detailed regulation in this area is demonstrated, we think its imposition would do more harm than good.

§ 2.53 Governmental agencies.—Rules.

(a) *In general*. Where research, audit, or evaluation functions are performed by or on behalf of a State or Federal governmental agency, the minimum qualifications of personnel performing such functions may be determined by such agency, subject to the provisions of this part, with particular reference to the organizational requirements and limitations on the categories of records subject to review by different categories of personnel.

(b) *Financial and administrative records*. Where program records are reviewed by personnel who lack either the responsibility for, or appropriate training and supervision for, conducting scientific research, determining adherence to treatment standards, or evaluating treatment as such, such review should be confined as far as practicable to administrative and financial records. Under no circumstances should such personnel be shown caseworker or counsellor notes, or similar clinical records. Programs should organize their records so that financial and administrative matters can be reviewed without disclosing clinical information and without disclosing patient identifying information except where necessary for audit verification.

(c) *Scientific research and long-term evaluation studies.* No State and no agency or political subdivision of a State may require, as a condition to funding, licensing, or otherwise, that any program furnish patient identifying information for the purpose of conducting scientific research or long-term evaluation studies unless the recipient of such information is legally required to hold such information in confidence, is prohibited from taking any administrative, investigative, or other action with respect to any individual patient on the basis of such information, and is prohibited from identifying, directly or indirectly, any individual patient in any report of such research or evaluation, or otherwise disclosing patient identities in any manner.

(d) *Opinion and description to be furnished program.* Before any patient identifying information is required to be submitted by a program under the circumstances described in paragraph (c), the program shall be furnished—

(1) An opinion by the attorney general or other chief legal officer of the State to the effect that the conditions specified in paragraph (c) are fulfilled with respect to such program or with respect to all programs in such State similarly situated, and

(2) A description of the administrative procedures and physical limitations on access or other measures to provide for the security of the data, but such description shall not be in such detail as to furnish guidance for wrongful attempts to breach such security.

(e) *Exclusiveness of procedures.* No State or local governmental agency may require any treatment program to furnish patient identifying information to itself or any other recipient except in conformity with this section or § 2.54. No Federal agency may require any treatment program to furnish patient identifying information to itself or any other recipient except in conformity with this section (other than paragraph (d)(1) thereof) or § 2.54.

§ 2.53–1 Governmental agencies.—Basis and purpose.

Section 2.53 is an implementation of the authority contained in subsection (g) of the authorizing legislation to provide safeguards and procedures to effectuate the purposes of such legislation. It makes clear that whenever information is required of a program, whether by law or by the terms or conditions of a contract or grant, the procedures and safeguards required under this section are applicable.

§ 2.54 Patient identifying information in connection with examinations.—Rules.

(a) *Definitions.* For the purposes of this section—

(1) The term "examination" means any examination to which this section is made applicable by paragraph (b) of this section.

(2) The term "examiner" means any individual or any public or private organization, including any Federal, State, or local governmental agency, which conducts an examination to which this section applies.

(b) *Applicability.* This section applies to any examination of the records of a treatment program which is carried out for the purpose of or as aid to ascertaining the accuracy or adequacy of its financial or other records, or the efficiency or effectiveness of its financial, administrative, or medical management, or its adherence to financial, legal, medical, administrative, or other standards, regardless of whether such examination is called an audit, an evaluation, an inspection, or by any other name.

(c) *Statement required for disclosure of patient identifying information in connection with examination.* No program may make, and no examiner may require any disclosure of patient identifying information in connection with an examination unless the examiner furnishes to the program a written statement—

(1) that no record of patient identifying information will be made or retained by or on behalf of the examiner in connection with the examination without notice to the program in accordance with paragraph (c)(2) of this section, or

(2) setting forth the specific purpose for which a record of patient identifying information is being retained by or on behalf of the examiner, the location at which such information will be kept, and the name, official title, address, and telephone number of a responsible individual to whom any inquiries by the program about the disposition of such record should be directed.

(d) *Disposition of record of patient identifying information in connection with examination.* After any record of patient identifying information retained in connection with an examination has served its purpose, or within the time prescribed in paragraph (e) of this section, whichever is earlier, the examiner shall destroy or return to the program all records (including any copies thereof) containing patient indentifying information which have been in its possession in connection with such examination.

(e) *Maximum time allowed for disposition.* The action required by paragraph (d) shall be completed—

(1) Except as provided in paragraph (e)(2) of this section not more than two years after the record was acquired by or on behalf of the examiner, or

(2) Where the record is needed in connection with a formal legal proceeding against the program commenced or to be commenced not more than two years after the record was acquired, and written notice to this effect is furnished to the program within two years after the record was acquired, not later than the termination of such proceeding.

(f) *Notice of final disposition.* When an examiner disposes of records as required by paragraph (d) of this section, or not later than the time prescribed by paragraph (e) of this section, whichever is earlier, the examiner shall furnish to the program concerned a written statement—

(1) That there has been compliance with this section and with the provisions of this part prohibiting any disclosure of patient identifying information from records held by auditors or evaluators, or

(2) Specifying the particulars in which there has been a failure of compliance.

§ 2.54–1 Patient identifying information in connection with examinations.—Basis and purpose.

Confidence on the part of treatment program personnel in the integrity of auditing and regulatory processes is important to the effective functioning of the treatment system. It is the purpose of § 2.54 to foster practices which will both justify and engender such confidence.

§ 2.55 Supervision and regulation of narcotic maintenance and detoxification programs.—Rules.

(a) *Definition of "registrant".* For the purposes of this section, the term "registrant" means a person who (1) has pending an application for registration under section 303(g) of the Controlled Substances Act (21 U.S.C. 823 (g)), or (2) has been registered under such section and whose registration has not expired or been surrendered or revoked.

(b) *Drug Enforcement Administration.* Duly authorized agents of the Drug Enforcement Administration shall have access to the premises of registrants for the purpose of ascertaining compliance (or ability to comply) with standards established by the Attorney General under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) respecting the security of stocks of narcotic drugs and the maintenance of records (in accordance with section 307 of the Controlled Substances Act, 21 U.S.C. 827) on such drugs. Registrants shall maintain such records separate from and in addition to patients' clinical records required to be maintained under 21 CFR 310.505 (d)(7)(iii), which shall not be available to such agents except as authorized under a court order in accordance with Subpart E of this part. Records maintained by registrants for the purposes of section 307 of the Controlled Substances Act (21 U.S.C. 827) need not identify patients by name, address, social security number, or otherwise except by an identifying number assigned by the registrant, but where such a system is used, the registrant shall maintain on a current basis a cross-index referencing each identifying number to the name and address of the patient to whom it refers. Upon request at any time and without advance notice, but subject to the provisions of § 2.54, such agents shall be granted immediate access to any such index. Such agents may use names and addresses so obtained strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information so obtained may not be compiled or used in any registry or personal data bank of any description.

(c) *Food and Drug Administration.* Duly authorized agents of the Food and Drug Administration shall have access to the premises of registrants and to all records maintained by registrants, for the purpose of ascertaining compliance (or ability to comply) with standards established by the Secretary of Health, Education and Welfare under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (42 U.S.C. 257a), sections 303(g)(1) and 303(g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(1) and 823(g)(3)), and sections 505 and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and 371(a)). When necessary in the conduct of their duties, and subject to the provisions of § 2.54, agents may use names and addresses of patients strictly for the purposes of auditing or verifying program records, and shall exercise all reasonable precautions to avoid inadvertent disclosure of patient identities to third parties. Names and other identifying information on patients obtained pursuant to this section or by any other compulsory process may not be compiled or used in any registry or personal data bank of any description. Except as authorized under this paragraph or by a court order granted under Subpart E of this part, (1) such agents may not, either orally or in writing, except in conversation with personnel of the registrant while on the premises of the registrant, identify any patient otherwise than by reference to an identifying number assigned by the registrant, and (2) such agents may not remove from the premises of the registrant any notes, documents, or copies thereof which contain patient identifying information.

(d) *State drug law enforcement agencies.* Duly authorized agents of any State drug law enforcement agency having jurisdiction and specific responsibility by statute or otherwise for the enforcement of criminal laws relating to controlled substances (as defined in the Controlled Substances Act) shall have access to the premises of any registrant for the purposes (with respect to corresponding provisions, if any, of State law) and subject to the restrictions and limitations set forth in paragraph (b) of this section, and subject to § 2.54.

(e) *State health authorities.*

(1) *Definition of "qualified State health agency".* As used in this paragraph, the term "qualified State health agency" means an agency of State government (i) which has express legal responsibility to ascertain that registrants under its jurisdiction comply with appropriate treatment standards; (ii) which is legally and administratively separate from any agency of State government responsible for investigation of violations of, or enforcement of, criminal law generally or criminal laws relating to controlled substances; (iii) whose personnel are qualified by training or experience to conduct inspections of health care facilities to ascertain compliance with treatment standards; and (iv) whose personnel are by State law, or by published administrative directive enforced by effective sanctions, required to maintain the confidentiality of any information concerning the identity of patients which they may acquire in the course of their official duties.

(2) *Access.* Duly authorized agents of a qualified State health agency shall have access to the premises of registrants and to all records maintained by registrants, for the purpose of ascertaining compliance (or ability to comply) with treatment standards (including those relating to quantities of narcotic drugs which may be provided for unsupervised use by individuals in treatment) established under State law. Such access, and the use of any information thereby obtained, shall be subject to the restrictions and limitations set forth in paragraph (c) of this section, and subject to § 2.54.

§ 2.55–1 Supervision and regulation of narcotic maintenance and detoxification programs.—Basis and purpose.

(a) Section 2.55 is addressed to the general problem described in the following passage from the legislative history of Pub. L. 93–282:

> A major element of the task of fashioning new regulations pursuant to the express rulemaking authority conferred by this legislation will be to reconcile the sometimes conflicting interests of research, audit, and evaluation with rights of privacy and the confidentiality of the relationship between patient and clinician. Such a reconciliation becomes particularly crucial where the functions of research, audit, or evaluation are conducted by a governmental agency with regulatory powers and responsibility, and the treatment involves the use of a drug such as methadone which is in a research status or which is readily susceptible of misuse or illicit diversion.
>
> Because of the difficulty and complexity of the task, the rulemaking authority is intentionally cast in terms broad enough to permit the limitation of the scope, content, or circumstances of any disclosure under subsection (b), whether (b)(1) or (b)(2), in the light of the necessary purposes for which it is made or required. (Congressional Record, daily edition, May 8, 1974, page H3563).

(b) It has been the consistent interpretation of the Special Action Office for Drug Abuse Prevention that the only provision of the authorizing legislation which permits disclosures to compliance officers, whether of DEA, FDA, or state agencies, is subsection (b)(2)(B). That subsection strictly prohibits any further disclosure of names or other identifying information concerning patients, and the statutory prohibition has been buttressed by provisions of these regulations, notably § 2.54, providing safeguards and procedures to assure that the statutory prohibition is respected.

(c) In testimony and written comment on the August 22, 1974 draft of these regulations, it has been urged that access to patient identifying information by law enforcement personnel, even for the limited purposes allowed by statute and regulation, should be prohibited except pursuant to a court order obtained under 21 U.S.C. 1175(b)(2)(C). We believe that such a prohibition is beyond our power to impose.

(d) Section 307(b) of the Controlled Substances Act (21 U.S.C. 827) provides, in pertinent part, "Every * * * record required under this section * * * shall be kept and be available, for at least two years; for inspection and copying by officers or employees of the United States authorized by the Attorney General." It is a well known principle of statutory construction that amendments and repeals by implication are not favored. In *People v. Newman*, 32 N.Y.2d 379, 345 N.Y.S.2d 502, 298 N.E.2d 651 (1973), cert. denied 414 U.S. 1163, 94 S.Ct. 927, 39L. Ed. 2d 116 (1974), the United States filed *amicus* briefs with the Court of Appeals of New York and with the United States Supreme Court, arguing that section 408 of Pub. L. 92–255 (21 U.S.C. 1175) did not effect an implied amendment or repeal of the provisions of Pub. L. 91–513 (21 U.S.C. 872(c) and 42 U.S.C. 242a(a)) which confer on the Attorney General and the Secretary of Health, Education, and Welfare the power to grant the so-called research privilege discussed in § 2.24. This position was expressly adopted by the New York court. We cannot now take the inconsistent position that section 408 of Pub. L. 92–255 did indeed amend by implication section 307 of Pub. L. 91–513, particularly in the face of a contrary contemporaneous administrative interpretation by both the Special Action Office for Drug Abuse Prevention and the Department of Justice. In short, if the right of access and copying conferred on Federal agents by 21 U.S.C. 827 is to be amended to provide that it may only be exercised pursuant to a court order in the case of maintenance and detoxification programs, that is a change which must be wrought by the Congress.

(e) In the case of inspections carried out by health supervisory agencies, we think that denial of access to any documents showing patient identifying information may have a serious adverse effect on the validity of the inspection process. Even if a program keeps its own records in terms of patient-identifying numbers assigned by the program, the patient file may contain—may, indeed, be required to contain—documents signed by the patient or originating outside the program. Where signatures, names, and addresses are all obliterated, it is impossible for the inspector to check the file even for apparent internal consistency. We believe that outright forgery is and will remain a rarity, but the temptation to cover improper or inadequate documentation by "accidental misfilings" may be something else again.

(f) From a legal standpoint, the term "audit" has long comprehended the notion of external verification. In a commercial setting, this means that at least some inventory will actually be counted, at least some receivables will be verified by contacting the customers, and so on. To rule that this crucial aspect of the audit process cannot be carried out with respect to a treatment program until after the auditor goes through the procedure of obtaining a specific court order under subsection (b)(2)(C) would seem to contravene the intent of subsection (b)(2)(B).

(g) In all of this, our decisions must be illuminated by a balanced consideration of the best interests of the patient no less than a desire to foster the implementation of cherished values in society at large. If protection of the patient's right to privacy is achieved by means which seriously impair our ability to protect him from exploitation and malpractice, not to mention the diversion of funds intended for his benefit, it would be a hollow victory indeed. We believe that the procedures and safeguards which these regulations impose on the conduct of audits and evaluations will avoid that result, while affording substantial and meaningful new protection to the confidentiality of patient records.

§ 2.56 Prohibition on disclosure of patient identities from research, audit, or evaluation records—Rules.

Where the content of patient records has been disclosed pursuant to this subpart for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State. This prohibition does not affect the accessibility of the original records under authority of a court order referred to in subpart E.

§ 2.56–1 Prohibition on disclosure of patient identities from research, audit, or evaluation records—Basis and purpose.

Section 2.56 restates the prohibition on further disclosure which is contained in subsection (b)(2)(B) of the authorizing legislation. The relationship of the provisions authorizing court orders to the provisions authorizing disclosure for research, audit, and evaluation, is dealt with in § 2.62.

Subpart E—Court Orders

§ 2.61 Legal effect of order—Rules.

Subsection (b)(2)(C) of the sections which authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582) empowers the courts, in appropriate circumstances, to authorize disclosures which would otherwise be prohibited by subsection (a) of those sections. Subsection (b)(2)(C) operates only as a mechanism for the relief of the duty imposed by subsection (a) and not as an affirmative grant of jurisdiction to authorize or compel disclosures prohibited or privileged by other provisions of law, whether Federal or State. An order or provision of an order based on some other authority, or a subpoena, or other appropriate legal process, is required to compel disclosure. To illustrate, if a person who maintains records subject to this part is merely requested, or is even served with a subpoena, to disclose information contained therein in a manner prohibited in the absence of a court order, he must refuse such a request unless, and until, an order is issued under subsection (b)(2)(C). Such an order would remove the prohibition, but could not, of its own force, require disclosure. If there were no subpoena or other compulsory process, or a subpoena had been issued but had expired or been quashed, the custodian of the records would have discretion as to whether to disclose the information sought unless and until disclosure were ordered by means of appropriate legal or administrative process, the authority for which would have to be found in some source other than subsection (b)(2)(C) of the sections authorizing this part.

§ 2.61–1 Legal effect of order—Basis and purpose.

(a) Section 2.61 is a restatement of the interpretative rules embodied in §§ 1401.61 and 1401.62 of the previous regulations. Both the positioning of the authority to issue court orders in S. 2097 as initially passed by the Senate (92nd Congress, 1st Session, December 2, 1971) and the explicit cross-reference in section 408(a) of Pub. L. 92-255 make clear the congressional intent that section 408(b)(2)(C) operate as a mechanism for the relief of the 408(a), strictures and not as an affirmative grant of jurisdiction to authorize disclosures prohibited by other provisions of law, whether Federal or State.

(b) The amendment made by Pub. L. 93-282 to section 333 of the Alcoholism Act (42 U.S.C. 4582) was enacted with the same language and structure as section 408 in this regard in order to make the interpretative rules set forth in § 2.61 applicable to it.

§ 2.62 Inapplicability to secondary records—Rules.

The authority which subsection (b)(2)(C) of the sections which authorize this part (21 U.S.C. 1175 and 42 U.S.C. 4582) confers on courts to issue orders authorizing the disclosure of records applies only to records referred to in subsection (a) of such sections, that is, the records maintained by treatment or research programs which have patients, and not to secondary records generated by the disclosure of the subsection (a) records to researchers, auditors, or evaluators pursuant to subsection (b)(2)(B).

§ 2.62–1 Inapplicability to secondary records—Basis and purpose.

(a) The interpretative rule set forth in § 2.62 is an essential and basic limitation on the scope of (b)(2)(C) orders. It was part of the original regulations under section 408 of Pub. L. 92-255 published November 17, 1972 (37 FR 24638), and was carried forward unchanged in the amended regulations published December 6, 1973 (38 FR 33748), the special status of which has already been noted in § 2.3. See, also, § 2.61–1.

(b) Although this rule is well supported by the history and technical structure of the legislation, the policy considerations in its favor are even more compelling. In § 2.52–1, we have discussed the urgent necessity for access, even without patient consent, to patient records on the part of qualified personnel engaged in scientific research and evaluation. Where this access includes patient identifying information, as it sometimes must if vital work is to be done, there must not be any question whatsoever about the legal inviolability of its confidential status in the hands of the researcher. Granted, there may occur rare occasions when the original records are for some reason not available, where a (b)(2)(C) order would lie as to the original records, and where there would seem to be some advantage in the administration of justice for such an order to permit disclosure of identifying information by the researcher. But compared to the damage which the mere potentiality for access does to the whole research enterprise, the advantage in terms of ability to deal with rare and anomalous cases seems almost trivial. Even in those cases, denial of access to the party seeking the information leaves him in no worse position than if the research or evaluation, which was certainly not undertaken for his benefit, had never been done at all.

(c) Where the secondary records are generated under the circumstances described in § 2.54, of course, this argument does not apply. In that situation, if preliminary examination suggests that the records may be needed for compliance or other administrative or judicial proceedings, the person conducting the audit or other examination should promptly seek the authority of a court order to copy the original records. The use of secondary records thus generated under authority of a court order would then be limited by the terms and purposes of the order, rather than subsection (b)(2)(B) of the authorizing legislation, and thus the rule set forth in § 2.62 would not apply.

§ 2.63 Limitation to objective data—Rules.

(a) *Limitation to objective data.* Except as provided in paragraph (b) of this section, the scope of an order issued pursuant to this subpart may not extend to communications by a patient to personnel of the program, but shall be limited to the facts or dates of enrollment, discharge, attendance, medication, and similar objective data, and may include only such objective data as is necessary to fulfill the purposes for which the order is issued.

(b) *Exception.* When a patient in litigation offers testimony or other evidence pertaining to the content of his communications with a program, an order under this subpart may authorize the submission of testimony or other evidence by the program or its personnel.

§ 2.63–1 Limitation to objective data.—Basis and purpose.

In the three-year period subsequent to the original enactment of 21 U.S.C. 1175, not a single occasion was reported to the Special Action Office for Drug Abuse Prevention on which an attempt was made to secure a (b)(2)(C) order authorizing the disclosure of a confidential communication by a patient to a counsellor or other member of the staff of a treatment program. In all of the comments and testimony received on the draft regulations published August 22, 1974, there was nothing to suggest any circumstances under which a court order authorizing such a disclosure would be either desirable or appropriate. Yet the mere possibility that such an order might be issued is to some a source of anxiety which impairs the effectiveness of treatment. Such an ongoing negative effect clearly outweighs the remote theoretical possibility that some peculiar circumstance might arise in which judicial authorization for such a disclosure might be sought. Accordingly, the limitation imposed by § 2.63 on the scope of (b)(2)(C) orders to preclude that possibility, and hence to eliminate its adverse influence on treatment services, appears to be a proper exercise of rulemaking power.

§ 2.64 Procedures and criteria in general—Rules.

(a) *Identity of patient.* Applications for court orders to authorize disclosure of records pertaining to a known patient shall not use the real name of the patient unless the patient consents thereto voluntarily and intelligently. In the case of an *ex parte* application initiated by the patient, the application should be instituted in the name of a fictious person, such as Jon Doe, unless the patient requests otherwise. The same procedure should be followed in the case of a separate proceeding held in conjunction with a pending criminal or civil action. Any court order should identify the patient fictitiously, and the disclosure of the patient's real name should be communicated to the program in such manner as to protect the confidentiality of the patient's identity.

(b) *Notice.* In any proceeding not otherwise provided for in this subpart, in which the patient or the program has not been made a party, each shall be given appropriate notice and an opportunity to appear in person or to file a responsive statement, deposition or other form of response consistent with local rules of procedure. The court shall give due consideration to any such statement, deposition or other response in exercising its discretion as to the existence of good cause and, if deemed necessary or desirable, consistent with local rules of procedure, it may order the program director to appear and give direct testimony.

(c) *Hearings.* All hearings and all evidence in connection therewith shall be held or taken in the judge's chambers, unless the patient requests an open hearing or the court determines that such hearing is consistent with the public interest and the proper administration of justice.

(d) *Good cause.* No order shall be issued unless the record shows that good cause exists, and in assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

(e) *Need for disclosure.* If other competent evidence or sources of information are available, the court should ordinarily deny the application.

(f) *Adverse effects.* If there is evidence that disclosure would have an adverse effect upon successful treatment or rehabilitation of the patient or would impair the effectiveness of the program, or other programs similarly situated, in the treatment or rehabilitation of other patients, the application should be denied unless the court finds that the adverse effects are outweighed by other factors.

(g) *Content of order.* Any order authorizing disclosure shall—

(1) Limit disclosure to those parts of the patient's record deemed essential to fulfill the objective for which the order was granted;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include any other appropriate measures to keep disclosure to a minimum for the protection of the patient, the physician-patient relationship and the treatment services.

(h) *Applications not otherwise provided for.* In any case not otherwise provided for in this subpart, application for an order authorizing disclosure of records to which this part applies may be made by any person who has a legally cognizable interest in obtaining such disclosure.

§ 2.64–1 Procedures and criteria in general.—Basis and purpose.

Section 2.64, in accordance with subsection (g) of the authorizing legislation, sets out procedures and criteria for the issuance of (b)(2)(C) orders in general, subject to the more specific provisions with respect to particular types of proceedings covered in the succeeding sections of this subpart.

§ 2.65 Investigation and prosecution of patients.—Rules.

(a) *Applicability.* This section applies to any application by an investigative, law enforcement, or prosecutorial agency for an order to permit disclosure of patient records for the purpose of conducting an investigation or prosecution of an individual who is, or who is believed to be, a present or former patient in a program.

(b) *Notice.* Except where an order under § 2.66 is sought in conjunction with an order under this section, any program with respect to whose records an order is sought under this section shall be notified of the application and afforded an opportunity to appear and be heard thereon.

(c) *Criteria.* A court may authorize disclosure of records pertaining to a patient for the purpose of conducting an investigation of or a prosecution for a crime of which the patient is suspected only if the court finds that all of the following criteria are met:

(1) The crime was extremely serious, such as one involving kidnapping, homicide, assault with a deadly weapon, armed robbery, rape, or other acts causing or directly threatening loss of life or serious bodily injury, or was believed to have been committed on the premises of the program or against personnel of the program.

(2) There is a reasonable likelihood that the records in question will disclose material information or evidence of substantial value in connection with the investigation or prosecution.

(3) There is no other practicable way of obtaining the information or evidence.

(4) The actual or potential injury to the physician-patient relationship in the program affected and in other programs similarly situated, and the actual or potential harm to the ability of such programs to attract and retain patients, is outweighed by the public interest in authorizing the disclosure sought.

(d) *Scope.* Both disclosure and dissemination of any information from the records in question shall be limited under the terms of the order to assure that no information will be unnecessarily disclosed and that dissemination will be no wider than necessary. Under no circumstances may an order under this section authorize a program to turn over patient records in general, pursuant to a subpoena or otherwise, to a grand jury or a law enforcement, investigative, or prosecutorial agency.

(e) *Counsel.* Any application to which this section applies shall be denied unless the court makes an explicit finding to the effect that the program has been afforded the opportunity to be represented by counsel independent of counsel for the applicant, and in the case of any program operated by any department or agency of Federal, State, or local Government, is in fact so represented.

§ 2.65–1 Investigation and prosecution of patients—Basis and purpose.

(a) The need for objective criteria for the issuance of court orders in connection with investigation or prosecution of patients seems particularly pressing. In the absence of such criteria, the assurance of confidentiality otherwise provided for by the authorizing legislation may be felt to be of little value.

(b) It has not been found possible to frame entirely satisfactory rules for the scope of orders under § 2.65, but an illustration may be helpful. Where a witness to a crime is believed capable of identifying a suspect by appearance, and the criteria set forth in § 2.65(c) are met, and the program has photographs of its patients, the witness alone may be permitted to view the photographs, with no names attached. If the witness failed to identify any photograph as being a picture of the suspect, that would end the matter. If there was such an identification, the program would be authorized to give any information in its possession as to the suspect's identity and whereabouts to appropriate authorities.

(c) It is not the purpose of this section to substitute a mechanical formula for judicial discretion, but rather to provide criteria which define the area within which discretion is to be exercised. The reason for including all crimes committed on program premises or against program personnel is not any special solicitude for programs as opposed to other victims of crime, but is rather the result of the special difficulties which the broad definition of "records" in § 2.11(o) creates for program personnel as complaining witnesses.

(d) In regard to § 2.65(e), experience has demonstrated that independent counsel may be of crucial importance. The leading case construing 21 U.S.C. 1175, *People v. Newman*, 32 N.Y.2d 379, 345 N.Y.S.2d 502, 298 N.E.2d 651 (1973); certiorari denied, 414 U.S. 1163, 94 S.Ct. 927, 39 L. Ed.2d 116 (1974), would never have been presented to the courts but for the fact that legal counsel for Dr. Newman was furnished on a *pro bono publico* basis by a private law firm. In an entirely different case, a United States District Court appears to have issued a wholly inappropriate order under 21 U.S.C. 1175 in a case in which the treatment program involved was operated by an agency of the United States Government, and either was unrepresented, or was represented by the same attorney who represented the agency seeking the order. It is possible, of course, that the order would have been issued in any event, but it seems clear that there was no adequate presentation to the court of arguments or testimony in opposition. It is difficult to see how the purposes of subsection (b)(2)(C) of the authorizing legislation can be carried out if there is inadequate presentation of the issues to the courts which must decide them.

§ 2.66 Investigation and prosecution of programs.—Rules.

(a) *Applicability*. This section applies to any application by an administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency for an order to permit disclosure of patient records or the making of copies thereof (including patient identifying information) for the purpose of conducting an investigation or an administrative or judicial proceeding with respect to any program or any principal, agent, or employee thereof in his capacity as such.

(b) *Notice*. An application under this section may, in the discretion of the court, be granted without notice, but upon the implementation of any order so granted, the program shall be afforded an opportunity to seek the revocation or amendment of such order.

(c) *Scope*. Both disclosure and dissemination of any information from the records in question shall be limited under the terms of the order to assure that patient identities will be protected to the maximum practicable extent, and that names and other identifying characteristics of patients are expunged from any documents placed in any public record. No information obtained pursuant to an order under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65.

§ 2.66–1 Investigation and prosecution of programs—Basis and purpose.

The principal purpose of § 2.66 is to enable a regulatory agency whose inspection or other source of information has disclosed a need for follow-up, or which has been refused access to patient records, to obtain the necessary authorization for access and copying. There may also be rare instances, such as those involving financial fraud, tax evasion, or other offenses where access by other investigative agencies is necessary, subject to the requirements and protections of this part.

§ 2.67 Undercover agents and informants—Rules.

(a) *Applicability*. This section applies to any application by an administrative, regulatory, supervisory, investigative, or law enforcement agency for an order to permit such agency to have an undercover agent or informant in a program under circumstances which would otherwise be prohibited under § 2.19.

(b) *Notice*. An order under this section may be granted without notice where the criminal conduct for the investigation of which it is granted is believed to be carried on by the program director or by any employee or agent of the program with the knowledge of the program director or under such circumstances that in the exercise of reasonable care the program director should know of such conduct. Under any other circumstances, an order under this section may be granted only after the program director has been afforded notice and opportunity for hearing.

(c) *Criteria*. An order under this section may be granted only where there is reason to believe that a program or any principal, agent, or employee thereof is engaged in serious criminal misconduct, and that other means of securing evidence of such criminal misconduct are not available or would not be effective.

(d) *Scope*. An order granted pursuant to this section may authorize the use by the applicant of an undercover agent or informant, either as a patient or as an employee, of the program in question.

(e) *Time periods*. An order under this section may not authorize the use of an undercover agent for an initial period exceeding 60 days. At any time prior to the expiration of such 60-day period, the applicant may apply for an order extending such period for an additional period not to exceed 60 days, but in no event may the use of an undercover agent in any program be authorized for more than 180 days in any period of 12 consecutive months.

(f) *Duty of agent*. Except to the extent expressly authorized in an order under this section, which shall be limited to disclosure of information directly related to the purpose for which the order is granted, an undercover agent or informant shall for the purposes of this part be deemed an agent of the program within which he is acting as such, and as such shall be subject to all of the prohibitions of this part applicable to disclosures of any information which he may acquire.

§ 2.67–1 Undercover agents and informants—Basis and purpose.

The legal rationale underlying this section has been set forth in § 2.19–1. It is expected that this section will find its principal and perhaps its exclusive application in the area of drug law enforcement. Experience has demonstrated that medical personnel, no matter how credentialed, can engage in the illicit sale of drugs on a large scale, and that the use of undecover agents and informants is normally the only effective means of securing evidence sufficient to support a successful prosecution.

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Title 21—Food and Drugs

CHAPTER III—SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

PART 1401—CONFIDENTIALITY OF DRUG ABUSE PATIENT RECORDS

Revocation of Part

On May 9, 1975, there was published in the FEDERAL REGISTER (40 FR 20542) a notice of proposed rulemaking proposing the revocation of Part 1401 of Title 21 of the Code of Federal Regulations by reason of the proposed incorporation of its subject matter in a new Part 2 of Title 42 of the Code of Federal Regulations.

Interested persons were invited to submit written comments, views, or arguments with respect to the proposed revocation, within 30 days of the date of publication of that notice. None were received, except to the extent that they were implicit in those submitted on the proposed new Part 2 of Title 42 of the Code of Federal Regulations, which were duly considered.

Accordingly, pursuant to the authority of section 408 of the Drug Abuse Office and Treatment Act of 1972, as amended by Pub. L. 93–282 (21 U.S.C. 1175), and under the authority delegated to the General Counsel (39 FR 17901, May 21, 1974), Part 1401 of Title 21 of the Code of Federal Regulations is revoked, effective August 1, 1975.

Dated: June 25, 1975.

GRASTY CREWS, II,
General Counsel, Special Action Office for Drug Abuse Prevention.

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